BME Design-Fall 2025 - ALLISON RAUSCH
Complete Notebook

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Team Contact Information

ARSHIYA CHUGH - Dec 08, 2025, 7:59 PM CST

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Project Description

ARSHIYA CHUGH - Dec 08, 2025, 8:01 PM CST

Course Number: Lab 308

Project Name: Arterial Coupler Re-design: Adjustable Stent/cuff Anastomosis

Short Name: Arterial Re-coupler

Project Description or Problem Statement:

To design a way to anastomose arterial vessels in microsurgery that saves operative time and is technically simpler than hand sewing.

Microsurgical arterial anastomosis is a critical step in reconstructive, transplant, and trauma surgery, where the restoration of uninterrupted blood flow determines tissue viability and surgical success. Traditionally, arterial anastomoses are performed using hand-sewn microsutures under an operating microscope. While the gold standard for decades, this technique is technically demanding, time-intensive, and associated with a steep learning curve. Even in experienced hands, prolonged clamp time can increase ischemia risk, and suture-related trauma to the vessel wall can contribute to thrombosis, intimal hyperplasia, or anastomotic failure.

Existing mechanical coupling devices have simplified venous anastomoses in some settings, but their application to arterial vessels is limited. Arteries differ from veins in their thicker, more elastic walls, higher intraluminal pressures, and greater tendency for spasm. These anatomical and physiological differences present unique challenges for mechanical connection—requiring secure, hemostatic, and atraumatic fixation while maintaining luminal patency and minimizing turbulence.

A novel arterial coupling solution has the potential to:
• Reduce operative time and ischemia duration.
• Decrease reliance on advanced microsurgical skill for primary vessel connection.
• Improve reproducibility and consistency of outcomes across surgical teams.
• Minimize vessel wall manipulation, thereby reducing the risk of thrombosis.
• Expand access to high-quality microsurgical care in settings with limited subspecialty expertise.

Recent advances in biomaterials, microfabrication, and device engineering—combined with improved understanding of hemodynamics—offer a unique opportunity to design an arterial coupling system specifically tailored to the mechanical and physiological demands of arterial repair.
This project seeks to bridge the gap between current hand-sewn microsurgical standards and the need for a faster, safer, and more accessible method of arterial anastomosis. While there are many ways to design this sort of device, one idea that could work is designing “cuff anastomosis” that has an expandable external stent which combines a method currently used in animal studies with stent technology that exists for endovascular approaches.

Client: Dr. Jasmine Craig, Dr. Weifeng Zeng at UW Health

2025/09/10 - Intial Client Meeting to Understand Project Scope and Goals

ARSHIYA CHUGH - Dec 08, 2025, 7:59 PM CST

Title: Intial Client Meeting to Understand Project Scope and Goals

Date: 09/10/2025

Content by: All

Present: Ally Rausch, Jackie Behring, Sofia Decicco, Arshiya Chugh, Daniel Pies

Goals: The goal of this entry is to document a list of questions that the team will organize prior to the fiorst client meeting. This way we can ensure the team has completed individual research and has topics for discussion ready prior to meeting.

Content:

Question List:

- Design Specifications
  - How important is device reusability vs. single-use from a clinical and cost perspective?
  - What are the most critical performance metrics?
  - Are there size ranges / specific vessel types seen as a main priority?
  - What material or biocompatibility requirements would be most important for the device?
- Current Challenges
  - What problem in current procedures is most critical to solve - time, skill, outcomes, accessibility?
  - How much of a barrier is operative time in your procedures, and what reduction in time would be meaningful?
  - Do you see limitations with existing coupler or stent technologies that we should specifically try to overcome?
- Purchasing
  - What is the budget for this project?
  - How should we go about purchasing materials, do you want to purchase them or would you prefer to reimburse us?
- Clinical Need & Use Case
  - Are there specific patient populations (pediatrics, elderly, high-risk) where this device could have the greatest impact?
  - In practice, who would use this device most?
  - What risks are most critical for us to minimize with this design?
  - Is the primary purpose of this device to save time or to expand access (less skilled professionals can perform similar procedures with less technical skill/experience)

Conclusions/action items: Create product design specification. Continue team research. Begin brainstorming ideas.

2025/09/24 - Client Meeting to Discuss Product Design Specification and Design Matrix

ARSHIYA CHUGH - Dec 08, 2025, 7:58 PM CST

Title: Client Meeting to Discuss Product Design Specification and Design Matrix Ideas

Date: 09/24/2025

Content by: All

Present: Ally Rausch, Jackie Behring, Sofia Decicco, Arshiya Chugh, Daniel Pies

Goals: The goal of this meeting is to review the Product Design Specification document with the client. Aditionally, discuss design ideas and current mechanism ideas with the client and gauge feasibility.

Content:

1. How much overlap is required on each arterial surface?

- Not a maximum, whatever the artery will allow. A few millimeters at least to secure it without it popping it back off. The less the better generally, usually don't have a lot of vessel to work with.

2. Can the design puncture the artery? We want to add "spikes" of sorts to grip the artery/add traction to our device so what are the limitations on that? If it can puncture, does it matter if the spikes fully impale the artery, or would it be ok if the spikes did not fully puncture the artery?

- Design can puncture the artery if need be. Do not want it to go through to the lumen and stay there, but it can puncture the outside.

3. Where does dilation rank on your priorities for designs?

- Dialation is incredibly important. Starts at minimum and can expand larger + 0.3.

4. What is the maximum amount of sutures one of our designs could include? How long does it take to throw 1 suture (expert vs student)?

- Use 1 suture to wrap around the cuff.

Design 1 Feedback

The main challenge is inverting the arteries. The idea is to use a ring that flips one artery end inside out, then pull the second artery over it. Clamps on top will hold both arteries together, removing the need for sutures. This approach worked well in the straw experiment.

One important feature is that the diameter can be adjusted. The device should be able to expand a little larger than the vessel, so it can return to normal size if needed. Expansion should happen from the outside only. To do this, the design could have three small prongs between the cuff and the vessel wall that push outward, without going inside the artery.

Balloon mechanisms should not be used as all expansion must come from outside the vessel.

The device should work as a standalone system rather than relying on two devices. Clamps or sutures can provide extra support, but the design should mainly stay in place on its own.

Design 2 Feedback

The coupler needs to provide stable inversion without slipping or feeling unsupported. Once it's in place, it locks in and can't be removed easily.

Conclusions/action items: Incorporate feedback into designs. Refine design matrix and finalize designs. Send design matrix to client for review.

2025/11/05 - Client Meeting to Discuss Feasibility Testing and Material Order

ARSHIYA CHUGH - Dec 08, 2025, 8:14 PM CST

Title: Client Meeting to Discuss Feasibility Testing and Material Order

Date: 11/5/25

Content by: Arshiya Chugh

Present: Dr. Jasmine Craig, Ally Rausch, Jackie Behring, Sofia Decicco, Arshiya Chugh, Daniel Pies

Goals: Review proposed feasibility testing workflow. Confirm materials and prototype dimensions for the first round of testing. Align expectations regarding testing objectives and data collection.

Content:

The team presented the planned feasibility testing strategy using rigid stainless steel tubing as a stand-in for nitinol. Proposed tubing dimensions, target wall thicknesses, and inversion testing steps were reviewed.

Dr. Craig approved the plan to begin with rigid tubing to validate core mechanics before pursuing nitinol manufacturing. She confirmed that testing should prioritize artery inversion behavior, lumen preservation, and feasibility of deployment.

Material options were reviewed, and the team confirmed which tubing sizes to order for the next session. Dr. Craig emphasized the importance of documenting strain points and identifying where vessel damage or slippage occurs.

Conclusions/action items: Order stainless steel tubing in varied diameters and wall thicknesses. Prepare a structured feasibility testing protocol to bring to the next meeting. Bring all materials and tools for the first benchtop testing session.

2025/11/19 - Client Meeting for Initial Feasibility Testing using Machined Tubing

ARSHIYA CHUGH - Dec 08, 2025, 8:11 PM CST

Title: Client Meeting for Initial Feasibility Testing using Machined Tubing

Date: 11/19/25

Content by: Arshiya Chugh

Present: Dr. Jasmine Craig, Ally Rausch, Jackie Behring, Sofia Decicco, Arshiya Chugh, Daniel Pies

Goals: Conduct feasibility testing with the originally machined tubing. Assess artery inversion behavior and identify limitations in prototype geometry. Determine necessary modifications before next testing session.

Content:

The team met with Dr. Craig to test the machined stainless steel tubing segments using chicken thigh arteries. The group observed that the majority of tubing sections were still too long to allow proper vessel eversion and alignment.

Testing demonstrated that only the 3 mm tubing segment enabled successful inversion without excessive strain. Larger segments caused incomplete rollover, vessel stretching, and lumen distortion.

Dr. Craig provided feedback on procedure technique, geometry considerations, and the importance of refining stent height to match the mechanical capabilities of small-diameter arteries.

Conclusions/action items: Remachine tubing to 3–5 mm lengths to improve feasibility. Prepare additional tubing pieces for the next testing iteration. Adjust testing protocol to reflect updated dimensions and insertion technique.

2025/11/24 - Client Meeting for Second Trial of Feasibility Testing using Remachined Tubing

ARSHIYA CHUGH - Dec 08, 2025, 8:09 PM CST

Title: Client Meeting for Second Trial of Feasibility Testing using Remachined Tubing

Date: 11/24/25

Content by: Arshiya Chugh

Present: Dr. Jasmine Craig, Ally Rausch, Jackie Behring, Sofia Decicco, Arshiya Chugh, Daniel Pies

Goals: Validate feasibility of the updated tubing lengths (3–5 mm). Confirm inversion performance and identify acceptable prototype dimensions. Gather accurate data for final poster and report deliverables.

Content:

The team conducted a second round of feasibility testing using remachined tubing segments. The shortened tubing allowed consistent inversion, reduced vessel strain, and demonstrated improved alignment between the artery and the mock stent component.

Dr. Craig confirmed that the 3 mm length performed optimally and recommended using this dimension as the baseline for prototype design moving forward. The team recorded inversion quality, handling characteristics, and potential sources of slippage for the final analysis.

Consensus was reached that the refined geometry better reflects clinical constraints and should guide the next steps in stent and loader tube design.

Conclusions/action items: Adopt 3 mm tubing length as the current feasible dimension for prototype development. Use collected results in poster testing summary and final report. Prepare for next semester’s nitinol manufacturing and scaled-down testing.

2025/09/05 - Introductory Advisor Meeting to Discuss Project Goals and Scope

ARSHIYA CHUGH - Dec 08, 2025, 7:45 PM CST

Title: Advisor Meeting - Project Introduction & Expectations

Date: 9/5/25

Content by: Arshiya Chugh

Present: Prof. Darilis Suarez-Gonzalez, Ally Rausch, Jackie Behring, Sofia Decicco, Arshiya Chugh, Daniel Pies

Goals: Establish advisor expectations for the semester. Review project scope and upcoming client meeting. Align team responsibilities and early research tasks.

Content:

The advisor reviewed the general goals for the arterial anastomosis project and emphasized the importance of early research on existing coupling devices, biomaterials, and microsurgical constraints. Expectations for LabArchives documentation, professionalism in client communication, and weekly deliverables were clarified.

The team outlined questions planned for the upcoming client meeting and discussed the Product Design Specification (PDS) timeline. The advisor encouraged the team to clearly define device requirements early to streamline the design process.

Conclusions/action items: Begin gathering detailed literature for the PDS. Prepare for the first client meeting with a structured question list. Upload initial research to LabArchives.

2025/09/12 - Advisor Meeting to Discuss Product Design Specifications

ARSHIYA CHUGH - Dec 08, 2025, 7:49 PM CST

Title: Advisor Meeting to Discuss Product Design Specifications

Date: 9/12/25

Content by: Arshiya Chugh

Present: Prof. Darilis Suarez-Gonzalez, Ally Rausch, Jackie Behring, Sofia Decicco, Arshiya Chugh, Daniel Pies

Goals: Review PDS draft sections. Receive advisor feedback on performance requirements and constraints. Verify alignment between client expectations and PDS content.

Content:

The advisor reviewed the team's progress on the PDS and provided guidance on strengthening measurable performance metrics, including lumen consistency, adaptability, and deployment time. Recommendations were given for improving regulatory and safety considerations within the document.

The team clarified remaining uncertainties regarding sterilization requirements, material biocompatibility, and vessel size ranges. Advisor approved the planned structure and encouraged incorporating competitive device analysis.

Conclusions/action items: Complete remaining PDS sections for submission. Add more quantitative benchmarks for success criteria. Expand competitive device comparison within the PDS.

2025/09/26 - Advisor Meeting to Discuss Design Matrix and Preliminary Presentation

ARSHIYA CHUGH - Dec 08, 2025, 7:51 PM CST

Title: Advisor Meeting to Discuss Design Matrix and Preliminary Presentation

Date: 9/26/25

Content by: Arshiya Chugh

Present: Prof. Darilis Suarez-Gonzalez, Ally Rausch, Jackie Behring, Sofia Decicco, Arshiya Chugh, Daniel Pies

Goals: Review preliminary design concepts and evaluation criteria. Validate the design matrix structure and scoring. Confirm readiness for preliminary presentation preparation.

Content:

The team presented the three preliminary design concepts and the associated design matrix criteria. The advisor provided feedback on weighting certain categories, noting the importance of intraoperative usability and manufacturability.

Questions were raised regarding device locking mechanisms, expansion controllability, and expected vessel diameters. The advisor encouraged preparing visual sketches to aid in communicating concepts during the upcoming presentation.

Conclusions/action items: Finalize design matrix scoring and justification. Begin drafting the preliminary presentation. Continue researching expansion and locking mechanisms.

2025/10/17- Advisor Meeting to Discuss Transition to Prototyping and Challenges

ARSHIYA CHUGH - Dec 08, 2025, 7:52 PM CST

Title: Advisor Meeting to Discuss Transition to Prototyping and Challenges

Date: 10/17/25

Content by: Arshiya Chugh

Present: Prof. Darilis Suarez-Gonzalez, Ally Rausch, Jackie Behring, Sofia Decicco, Arshiya Chugh, Daniel Pies

Goals: Review modeling progress after preliminary presentation. Discuss feasibility of proposed designs. Outline expectations for early prototyping.

Content:

The advisor reviewed the updated design direction following the preliminary presentation. Feedback centered on ensuring geometric accuracy in the SolidWorks models and identifying materials suitable for prototyping.

The advisor emphasized evaluating manufacturability early, particularly for nitinol and alternative materials. Team discussed initial testing goals, including expansion performance and insertion feasibility. The advisor also encouraged contacting additional fabrication resources on campus.

Conclusions/action items: Finalize initial CAD models for printing. Proceed with identifying viable materials for early prototypes. Draft preliminary testing protocol for advisor review.

2025/10/24 - Advisor Meeting to Discuss Prototyping Constraints and Fabrication Progress

ARSHIYA CHUGH - Dec 08, 2025, 7:53 PM CST

Title: Advisor Meeting to Discuss Transition to Prototyping and Challenges

Date: 10/24/25

Content by: Arshiya Chugh

Present: Prof. Darilis Suarez-Gonzalez, Ally Rausch, Jackie Behring, Sofia Decicco, Arshiya Chugh, Daniel Pies

Goals: Review proposed stent geometries. Discuss challenges with nitinol sourcing and manufacturing. Plan for Show & Tell preparation.

Content:

The team presented updated research on stent geometries and the limitations associated with printing small-scale prototypes. The advisor recommended testing larger-scale models to validate deformation mechanics before committing to nitinol fabrication.

Budget limitations and sourcing difficulties were discussed, along with strategies for identifying cost-effective substitutes. The advisor provided guidance on what to prioritize for Show & Tell, including visual clarity of prototypes and a clear breakdown of manufacturability challenges.

Conclusions/action items: Print flexible large-scale stent models. Summarize fabrication challenges for presentation. Begin planning for feasibility testing using tubing.

2025/11/14 - Advisor Meeting to Discuss Feasibility Testing Review

ARSHIYA CHUGH - Dec 08, 2025, 7:56 PM CST

Title: Advisor Meeting to Discuss Transition to Prototyping and Challenges

Date: 11/14/25

Content by: Arshiya Chugh

Present: Prof. Darilis Suarez-Gonzalez, Ally Rausch, Jackie Behring, Sofia Decicco, Arshiya Chugh, Daniel Pies

Goals: Review feasibility testing plans. Evaluate tubing inversion behavior and prototype challenges. Plan for testing session.

Content:

The team shared outcomes from rigid tubing prototyping. Challenges and issues such as tubing wall thickness, vessel strain, and limited stent expandability were discussed. Advisor recommended reducing height of the tubing and exploring heat-treated nitinol patterns.

Feedback emphasized improving inversion consistency and documenting strain points. The advisor also encouraged collecting quantitative data to support poster preparation and simulation validation.

Conclusions/action items: Prepare smaller tubing segments (3–5 mm). Fabricate and heat-treat a woven nitinol stent prototype. Continue documenting all testing outcomes for the final poster.

2025/11/21 - Advisor Meeting to Discuss Testing Results and Final Poster Presentation

ARSHIYA CHUGH - Dec 08, 2025, 7:57 PM CST

Title: Advisor Meeting to Discuss Transition to Prototyping and Challenges

Date: 11/21/25

Content by: Arshiya Chugh

Present: Prof. Darilis Suarez-Gonzalez, Ally Rausch, Jackie Behring, Sofia Decicco, Arshiya Chugh, Daniel Pies

Goals: Review results from second feasibility testing session. Finalize prototype specifications for poster. Align expectations for final deliverables.

Content:

The team presented updated testing results and discussed improvements in inversion behavior after trimming tubing to shorter lengths. Advisor reviewed the stainless steel mock stent dimensions and provided feedback on how to refine the geometry for the final prototype.

Poster layout and content were discussed, including visuals for stent geometry, testing images, and data summaries. The advisor ensured the team's next steps aligned with clinical relevance and project goals.

Conclusions/action items: Finalize stent and loader tube dimensions for the poster. Complete poster figures and draft final report sections. Confirm alignment with team before poster submission.

2025/09/08 - Team Meeting to Discuss Product Design Specifications

ARSHIYA CHUGH - Dec 07, 2025, 1:59 PM CST

Title: Internal Team Meeting for Project Kickoff and Product Design Specifications

Date: 9/8/25

Content by: Arshiya Chugh

Present: Ally Rausch, Jackie Behring, Sofia Decicco, Arshiya Chugh, Daniel Pies

Goals: Establish early understanding of the project scope. Align on key objectives prior to the client meeting. Divide initial research responsibilities and plan early deliverables.

Content:

The team met to discuss the initial overview of the arterial anastomosis project. Members reviewed the problem statement, clarified expectations, and outlined key technical challenges in microsurgical anastomosis. The group identified focus areas for preliminary research, including existing coupling devices, biomaterials used in microvascular surgery, and current limitations of stent-based solutions.

The team drafted questions for the upcoming client meeting and discussed the structure of the Product Design Specification (PDS). Responsibilities for preliminary research and PDS background sections were delegated.

Conclusions/action items: Complete preliminary background research ahead of the client meeting. Finalize and refine the list of client questions. Begin outlining the PDS structure and gather early references.

2025/09/12 - Team Meeting for Product Design Specification Development

ARSHIYA CHUGH - Dec 07, 2025, 1:58 PM CST

Title: Internal Team Meeting for Product Design Specification Development

Date: 9/12/25

Content by: Arshiya Chugh

Present: Ally Rausch, Jackie Behring, Sofia Decicco, Arshiya Chugh, Daniel Pies

Goals: Finalize structure and content areas for the Product Design Specification (PDS). Consolidate research from Week 1 into clear design requirements. Align team contributions ahead of the upcoming PDS deadline.

Content:

The team met to organize and finalize the PDS draft following the initial client meeting. Members consolidated their individual research, focusing on device adaptability, biocompatibility, sterilization needs, and constraints related to microsurgical vessel sizes. The group reviewed competitive devices and existing stent geometries, translating findings into measurable design criteria. Responsibilities were assigned for completing remaining PDS sections, including regulatory considerations, performance metrics, and clinical needs.

The team confirmed the timeline for submission and reviewed expectations for LabArchives documentation.

Conclusions/action items: Complete assigned PDS sections by early next week. Upload research and references to LabArchives for unified documentation. Prepare to begin brainstorming preliminary design concepts after PDS submission.

2025/09/18 - Team Meeting for Preliminary Design Brainstorming

ARSHIYA CHUGH - Dec 07, 2025, 2:01 PM CST

Title: Internal Team Meeting for Preliminary Design Brainstorming and Concepts

Date: 9/18/25

Content by: Arshiya Chugh

Present: Ally Rausch, Jackie Behring, Sofia Decicco, Arshiya Chugh, Daniel Pies

Goals: Begin structured brainstorming for preliminary design concepts. Establish criteria for the design matrix. Identify mechanisms and features to explore further.

Content:

Following completion of the PDS, the team held an internal session to transition toward concept generation. Members shared initial sketches and researched mechanisms such as dilation systems, securing features, and adaptability strategies for variable vessel diameters.

The team identified key evaluation categories for the design matrix, including mechanical reliability, ease of deployment, manufacturability, and compatibility with microsurgical workflows. Research gaps were outlined, particularly regarding stent geometries, coupling interfaces, and materials suitable for small-scale vascular devices.

Conclusions/action items: Each member will draft 1–2 preliminary design concepts for the design matrix. Continue researching feasible dilation and locking mechanisms. Prepare questions for the next internal review session before matrix finalization.

2025/09/25 - Team Meeting to Finalize Design Matrix and Design Selection

ARSHIYA CHUGH - Dec 07, 2025, 2:03 PM CST

Title: Internal Team Meeting for Design Matrix Finalization and Design Selection

Date: 9/25/25

Content by: Arshiya Chugh

Present: Ally Rausch, Jackie Behring, Sofia Decicco, Arshiya Chugh, Daniel Pies

Goals: Finalize the preliminary design matrix and evaluate proposed concepts. Align on leading design directions for upcoming client review. Prepare content for the preliminary presentation.

Content:

The team met to review the three primary design proposals drafted during the week. Each design was evaluated against the criteria established earlier, including expansion reliability, safety, usability, and adaptability. Weighted scoring was discussed and adjusted based on team consensus.

Members refined sketches, clarified mechanisms, and resolved uncertainties ahead of sharing design concepts externally. The team also began outlining roles for the preliminary presentation and identified supporting background information required for the oral report.

Conclusions/action items: Complete all sections of the design matrix and finalize scoring. Begin building preliminary presentation slides and delegate speaking roles. Continue refining design sketches for clarity prior to the upcoming presentation.

2025/10/02 - Team Meeting for Preliminary Design Presentation Preparation

ARSHIYA CHUGH - Dec 07, 2025, 2:05 PM CST

Title: Internal Team Meeting for Preliminary Presentation Preparation

Date: 10/2/25

Content by: Arshiya Chugh

Present: Ally Rausch, Jackie Behring, Sofia Decicco, Arshiya Chugh, Daniel Pies

Goals: Finalize and rehearse the preliminary oral presentation. Confirm design matrix justification and chosen concepts. Align on next steps for modeling and early development.

Content:

The team met to complete the preliminary presentation materials, ensuring all slides aligned with the finalized design matrix and reflected client feedback. Presentation roles were assigned, and members practiced their sections, focusing on clarity of problem framing, design justification, and proposed mechanisms.

The group reviewed outstanding research tasks, particularly those related to nitinol behavior, stent geometries, and expansion mechanisms. Early SolidWorks modeling considerations were discussed to prepare for the upcoming transition into prototyping.

Conclusions/action items: Deliver the preliminary presentation and gather feedback for iteration. Begin initial SolidWorks modeling of selected design elements. Draft early testing and fabrication protocols for review next week.

2025/10/10 - Team Meeting to Discuss Preliminary Modeling and Prototyping Challenges

ARSHIYA CHUGH - Dec 07, 2025, 2:07 PM CST

Title: Internal Team Meeting for Preliminary Modeling and Prototyping

Date: 10/10/25

Content by: Arshiya Chugh

Present: Ally Rausch, Jackie Behring, Sofia Decicco, Arshiya Chugh, Daniel Pies

Goals: Begin early design development following the preliminary presentation. Establish modeling tasks and outline fabrication considerations. Shift team focus from documentation to physical prototyping preparation.

Content:

The team reviewed the feedback received from the preliminary presentation and aligned on revisions to be incorporated into the upcoming preliminary report. Members discussed requirements for transitioning into SolidWorks modeling and identified components that required finalized dimensions. Material sourcing began for initial prototypes, with considerations for nitinol, PTFE, and stainless steel. The team also outlined early fabrication strategies and defined the scope for the first round of testing protocols. Coordination for upcoming prototyping sessions was initiated.

Conclusions/action items: Begin SolidWorks modeling for selected design concepts. Continue material research and verify feasibility of fabrication methods. Draft testing and fabrication protocols for refinement next week.

2025/10/16 - Team Meeting for Continued Early Prototyping and Material Planning

ARSHIYA CHUGH - Dec 07, 2025, 2:10 PM CST

Title: Internal Team Meeting for Early Prototyping and Material Planning

Date: 10/16/25

Content by: Arshiya Chugh

Present: Ally Rausch, Jackie Behring, Sofia Decicco, Arshiya Chugh, Daniel Pies

Goals: Advance SolidWorks modeling and define prototype geometry. Evaluate materials and vendors for initial stent fabrication. Outline the preliminary testing framework.

Content:

The team met to review progress on early SolidWorks models and confirm dimensional parameters needed for prototyping. Members shared research on nitinol sourcing, tubing specifications, and potential fabrication methods.

The group discussed feasibility concerns regarding small-scale stent manufacturing and evaluated alternate materials to use during early testing.

Preliminary testing plans were outlined, including expansion behavior, vessel compatibility, and structural considerations. The team coordinated tasks for the upcoming prototyping phase and confirmed resource needs from the Makerspace and TeamLab.

Conclusions/action items: Complete initial CAD models and prepare files for printing. Identify and order materials required for early proto types.Finalize the outline for the preliminary testing plan.

2025/10/23 - Team Meeting to Discuss Geometry Refinement and Further Prototype Planning

ARSHIYA CHUGH - Dec 07, 2025, 2:14 PM CST

Title: Internal Team Meeting to Discuss Geometry Refinement and Further Prototype Planning

Date: 10/23/25

Content by: Arshiya Chugh

Present: Ally Rausch, Jackie Behring, Sofia Decicco, Arshiya Chugh, Daniel Pies

Goals: Refine stent geometry concepts for feasibility testing. Evaluate early fabrication strategies prior to Show & Tell. Plan next steps for materials and prototype preparation.

Content:

The team met to review progress on stent geometry research and assess how various strut patterns and widths could influence device mechanics.

Members discussed feedback from internal modeling efforts and identified dimensions requiring further iteration.

Prototype planning continued, with the team evaluating Makerspace materials that could approximate nitinol deformability for early demonstration models.

Members also aligned on what preliminary models would be printed ahead of Show & Tell and the specific design elements to highlight for peer feedback. The group reviewed fabrication limitations, budget considerations, and the need to explore cost-effective alternatives for early testing before committing to nitinol.

Conclusions/action items: Prepare and print additional stent prototype models in flexible resin. Finalize stent geometry options to bring to Show & Tell. Continue material research to identify viable substitutes for nitinol during early testing.

2025/10/30 - Team Meeting to Discuss Prototype Printing and November Planning

ARSHIYA CHUGH - Dec 07, 2025, 2:20 PM CST

Title: Internal Team Meeting to Discuss Prototype Printing and November Planning

Date: 10/30/25

Content by: Arshiya Chugh

Present: Ally Rausch, Jackie Behring, Sofia Decicco, Arshiya Chugh, Daniel Pies

Goals: Finalize 3D printing plans for preliminary stent prototypes. Establish the project timeline for November, including fabrication and testing milestones. Address feasibility concerns related to nitinol and small-scale manufacturing.

Content:

The team met at the Makerspace to discuss printing parameters, material choices, and potential issues related to scaling down the stent geometry. Members reviewed the limitations of 3D printers at this scale and considered alternative fabrication methods, including laser cutting and micro-machining.

Testing plans for November were drafted, with an emphasis on feasibility studies using metal tubing as a stand-in for nitinol. Budget constraints were also discussed, and the team revisited the cost implications of nitinol sourcing.

Additionally, the team prepared content for the upcoming Show & Tell by summarizing current obstacles and identifying key points for peer and advisor feedback.

Conclusions/action items: Print larger-scale flexible stent models for Show & Tell. Meet with TeamLab resources to evaluate manufacturing techniques. Draft manufacturing protocols and refine November testing timeline.

2025/11/06 - Team Meeting for Feasibility Testing Planning

ARSHIYA CHUGH - Dec 07, 2025, 2:20 PM CST

Title: Internal Team Meeting for Feasibility Testing Planning

Date: 11/6/25

Content by: Arshiya Chugh

Present: Ally Rausch, Jackie Behring, Sofia Decicco, Arshiya Chugh, Daniel Pies

Goals: Finalize feasibility testing protocol for upcoming evaluations. Align physical testing methods with planned simulation work. Prepare materials and tubing samples for initial benchtop testing.

Content:

The team reviewed feedback from Show & Tell and incorporated recommendations into the developing testing protocol. Members outlined the sequence of feasibility tests, including tubing insertion, eversion behavior, and preliminary expansion assessments.

Parallel progress in COMSOL modeling was discussed, with the team identifying flow and structural parameters that would need to match the physical testing environment. Tubing samples and metal segments were prepared for the next round of evaluations.

Planning focused on coordinating material availability, confirming measurements for test rig components, and outlining documentation expectations for the poster.

Show and Tell Feedback

- High temp sand bath
    - Neonatal Group 200
        - Set the nitinol themselves
- Outsource manufacturing for nitinol
    - Said somewhere at UW was cheap
- Research other materials that would be good for prototyping at such a small scale
- Other shape memory materials
- Reach out to medical device contract manufacturing companies (Cretex and Medical Murray)
- Look up existing stents and their geometry and why
- Talk to the Peeds Team
- Comsol is on all the CAE computers (easier to do if you have examples BME 550 (microfluidics) has examples for them and they will copy the settings and run it) (Dr. Avidad Hai)

Conclusions/action items: Finalize feasibility testing protocol and send to the client for review. Begin preparing stent and tubing samples for next week's testing session. Align COMSOL and physical testing parameters to ensure consistent data collection.

2025/11/13 - Team Meeting for Tubing Preparation & Early Testing Setup

ARSHIYA CHUGH - Dec 07, 2025, 2:23 PM CST

Title: Internal Team Meeting for Tubing Preparation & Early Testing Setup

Date: 11/13/25

Content by: Arshiya Chugh

Present: Ally Rausch, Jackie Behring, Sofia Decicco, Arshiya Chugh, Daniel Pies

Goals: Prepare tubing samples and stent materials for feasibility testing. Organize testing workflow and assign roles for upcoming evaluations. Continue refining COMSOL and SolidWorks testing protocols.

Content:

The team met to finalize materials needed for the upcoming testing session. Members prepared tubing by cutting sections to the appropriate lengths and confirming dimensional accuracy. The group also reviewed the stainless steel stent mock-up and discussed how its geometry would be evaluated during testing.

Updates were shared on simulation preparation, including early protocol drafting for COMSOL flow modeling and SolidWorks-based compression analysis. The team ensured that simulation goals aligned with the physical testing strategy.

Additionally, logistics for testing with the client were outlined, including data collection needs, documentation steps, and anticipated design adjustments.

Conclusions/action items: Complete tubing preparation and assemble all required testing materials. Finalize testing roles and sequence for the next feasibility session. Continue developing simulation protocols to compare with experimental results.

2025/11/20 - Team Meeting for Large-Scale Stent Prototype Fabrication

ARSHIYA CHUGH - Dec 07, 2025, 2:25 PM CST

Title: Internal Team Meeting for Large-Scale Stent Prototype Fabrication

Date: 11/20/25

Content by: Arshiya Chugh

Present: Ally Rausch, Jackie Behring, Sofia Decicco, Arshiya Chugh, Daniel Pies

Goals: Finalize fabrication of the large-scale nitinol stent prototype. Prepare tubing segments for feasibility testing at multiple lengths. Review initial testing feedback and plan the next iteration.

Content:

The team met to coordinate fabrication efforts following the machining and bending of the large-scale stent prototype. Members reviewed the nitinol wire weaving process and discussed steps for heat treatment, including proper handling and expected deformation behavior.

Tubing pieces were trimmed to smaller lengths to improve inversion feasibility during upcoming testing. The group evaluated material challenges encountered during cutting, including wall thickness and deformation concerns.

The team analyzed feedback from the most recent feasibility test and identified parameters to adjust in the next session, specifically stent height, flexibility, and vessel compatibility. Simulation progress was reviewed, and data requirements for the final poster were outlined.

Conclusions/action items: Heat-treat the woven nitinol stent and evaluate the resulting geometry. Prepare shorter tubing segments (3–5 mm) for the next testing round. Compile initial testing results for integration into poster and final report.

2025/12/03 - Team Meeting for Final Poster Preparation and Testing Feedback Review

ARSHIYA CHUGH - Dec 07, 2025, 2:28 PM CST

Title: Internal Team Meeting for Final Poster Preparation and Testing Feedback Review

Date: 12/3/25

Content by: Arshiya Chugh

Present: Ally Rausch, Jackie Behring, Sofia Decicco, Arshiya Chugh, Daniel Pies

Goals: Finalize the poster presentation and prepare deliverables. Review feasibility testing results and finalize prototype specifications for presentation. Ensure alignment with the client ahead of the poster session.

Content:

The team met to complete the final poster, integrating feasibility testing outcomes, stent prototype dimensions, and updated design rationale. Members verified data accuracy and ensured that all visual elements, including SolidWorks renderings and testing images, were polished for stakeholder review.

The group reviewed the stainless steel mock stent and loader tube geometry, confirming the final dimensions to be presented. Remaining feedback from the client was addressed, and the team discussed how to articulate next-semester goals during the presentation.

Final report responsibilities were assigned, and members outlined the remaining notebook entries and documentation required for course completion.

Conclusions/action items: Finalize and polish the poster for the December 5th presentation. Assemble the stainless steel stent and PTFE loader tube for demonstration. Complete remaining report sections and finalize individual notebook entries.

2025/12/06 - Updated Expenses BPAG Spreadsheet

ARSHIYA CHUGH - Dec 07, 2025, 2:41 PM CST

Title: Arterial Coupler Re-Design Semester Long Project Expenses

Date: 12/6/25

Content by: Arshiya Chugh

Present: N/A

Goals: Document project expenses related to prototype fabrication. Record material specifications and costs for budget tracking. Ensure transparency of project spending for final deliverables.

Content:

See attached expense spreadsheet below.

Conclusions/action items: Complete final deliverables. Add expense spreadsheet to the final report. Discuss final report with team.

ARSHIYA CHUGH - Dec 07, 2025, 2:42 PM CST

Download

BPAG_Expense_Spreadsheet.pdf (32.6 kB)

2025/12/02- Stent CAD Modeling and Prototype Planning

ARSHIYA CHUGH - Dec 09, 2025, 1:26 PM CST

Title: CAD Modeling and Prototype Planning

Date: 12/2/25

Content by: Jackie Behring

Present: All

Goals: Define device geometry and prepare for fabrication.

Content:

Steps**:**

- Open a new part file in SolidWorks and create the stent geometry based on client specifications (2–5 mm arterial range).
- Model wall thickness, barbed features, and overall height.
- Generate cross-sectional and isometric views to evaluate alignment and vessel fit.
- Export CAD files as needed for reference and communication with the team/client.

Conclusions/action items: Print scaled up resin model.

2025/12/02- SLA Resin Prototype Fabrication Outline

ARSHIYA CHUGH - Dec 09, 2025, 1:27 PM CST

Title: SLA Resin Prototype

Date: 12/02/25

Content by: Jackie Behring

Present: All

Goals: Produce a scaled-up physical model for visualization and workflow evaluation.

Content:

Steps:

- Upload the SolidWorks file to the UW Makerspace SLA printing system.
- Select standard rigid resin (non-elastic) for printing.
- Set print scale to a larger size (scaled-up prototype).
- Print the model and remove support structures after curing.
- Inspect the printed model for dimensional accuracy and visual alignment.
- Use this prototype for demonstrating device function and discussing workflow with the client.

Conclusions/action items: Create prototype that is to scale for feasibility testing.

2025/12/02 - Stainless Steel Prototype Fabrication Protocol and Steps

ARSHIYA CHUGH - Dec 09, 2025, 1:29 PM CST

Title: Stainless Steel Prototype Fabrication Outline and Steps

Date: 12/2/25

Content by: Jackie Behring

Present: All

Goals: Create a functional metal prototype for feasibility testing.

Content:

Materials:

- 316L stainless steel tubing (ID 2.31 mm, OD 2.54 mm, length 30.48 cm)
- Bandsaw (Design Innovation Lab)
- Fine-grit sandpaper
- Ruler/calipers

Steps:

- Measure and mark a 3 mm segment on the stainless steel tubing.
- Secure the tubing in the bandsaw jig to ensure a perpendicular cut.
- Cut one 3 mm section from the tubing.
- Inspect the cut edges for burrs or unevenness.
- Sand the edges carefully using fine-grit sandpaper until smooth.
- Verify the final length and edge smoothness using calipers.
- Clean the segment to remove filings and debris prior to testing.

Conclusions/action items: Utilize prototype for feasibility testing with client.

2025/12/08 - Flow Simulation SolidWorks Testing Protocol

ARSHIYA CHUGH - Dec 08, 2025, 9:15 PM CST

Title: Flow Simulation SolidWorks Testing Protcol

Date: 12/8/2025

Content by: Daniel Pies

Present: N/A

Goals: Define SolidWorks testing protocol for hoop stress and wall shear stress

Content:

1. Geometry preparation and assembly setup

- Import the arterial coupler / stent parts into a new SolidWorks assembly
- Verify that the artery lumen, stent, and any overlapping arterial segments are fully constrained and aligned along the global axial direction

2. Check geometry for flow analysis

- Confirm that the lumen forms a continuous, watertight internal volume with no unintended gaps or self-intersections
- Use Interference Detection and Check to identify overlapping bodies, tiny slivers, or non-manifold edges that may prevent meshing

3. Create internal lids at the inlet and outlet

- Use the Flow Simulation "Create Lids" tool on the open faces at the proximal and distal artery ends to close the domain for an internal flow study
- For any non-planar openings, manually sketch and extrude a thin cap surface/body to fully close the lumen

4. Define fluid and solid regions

- Start the Flow Simulation Wizard and specify an Internal analysis
- Select blood (or a Newtonian fluid with appropriate density and viscosity) for the internal fluid region
- Define the artery wall, stent, and surrounding solid components as solid regions to allow wall shear stress to be computed on their surfaces

Flow Simulation setup

5. Global settings

- Set the analysis type to Steady-state and enable Gravity if needed for orientation
- Specify fluid properties consistent with literature values for blood at 37 deg C

6. Boundary conditions

- At the inlet lid, apply a uniform velocity boundary condition of 0.2 m/s normal to the face
- At the outlet lid, apply an environmental pressure boundary condition so that the internal pressure field can develop naturally
- Set vessel walls and stent surfaces as no-slip walls

7. Operating and initial conditions.

- Set the operating pressure so that the resulting transmural pressure across the wall corresponds to 100 mmHg (0.0133 MPa)
- Use default initial flow conditions or initialize with a uniform velocity field along the lumen axis

8. Mesh definition

- Use the Global Mesh settings with Automatic type and then refine near critical regions
    - Apply local mesh refinement to the stent struts, overlap zones, and curved/bowed segments of the artery
    - Reduce minimum gap size and minimum wall thickness thresholds so the mesh resolves the stent strut spacing and arterial wall

9. Goals

- Define surface goals on artery and stent walls for average and maximum wall shear stress
- Define global goals for pressure drop between inlet and outlet and average velocity at selected cross-sections

10. Run the Flow Simulation

- Launch the solver and monitor convergence of global and surface goals
- Confirm that residuals and goal values have plateaued before accepting the solution

Post-processing Wall Shear Stress

11. Generate wall shear stress plots

- Insert Surface Plots on the inner arterial wall and stent surfaces with the parameter set to “Wall Shear Stress"
- Adjust color bar limits to highlight the range of interest and identify regions of peak shear, especially along bowed segments and at stent overlaps

12. Extract quantitative values

- Use Probe and Surface Parameters to record maximum and area-averaged wall shear stress values for each configuration
- Save images (cut plots and surface plots) and export numerical goal data for documentation

Structural analysis for Hoop Stress

13. Create a structural study using Flow results

- From the Flow Simulation results, start a new Static study and enable load transfer of fluid pressure onto the structural model
- Verify that the same artery-stent geometry is used and that material assignments match the intended properties

14. Fixtures and symmetry.

- Apply appropriate axial constraints to prevent rigid-body motion while allowing realistic radial deformation
- Use symmetry fixtures if only a sector of the model is analyzed

15. Loads

- Import the fluid pressure distribution from the Flow Simulation as an external load on the lumen surface (and, if desired, outer surfaces exposed to pressure)
- Confirm that the peak pressure corresponds to the desired 100 mmHg transmural loading

16. Run the static study

- Solve the structural model and generate a default von Mises stress plot to confirm that the solution is reasonable and free of singularities at constraints

17. Hoop stress extraction.

- Create stress plots using Principal Stresses and align the reference axis with the vessel centerline so that the first principal stress corresponds to circumferential (hoop) stress
- Use Section Views and Probe to sample hoop stress through the wall thickness and around the circumference for
    - Single arterial wall configuration
    - Nitinol stent alone
    - Full artery-stent-artery-artery stack

18. Data recording

- Record maximum and average hoop stress values for each configuration at 100 mmHg
- Compare the numerical results against thin-walled estimates and literature ranges for arterial and nitinol stresses

Conclusions/action items:

Refer to this entry for information on SolidWorks protocols for testing as needed.

2025/12/08 - Feasibility Testing Protocol and Results

ARSHIYA CHUGH - Dec 10, 2025, 3:45 PM CST

Title: Feasibility Testing Protocol and Results

Date: 12/8/2025

Content by: Sofia

Present: N/A

Goals: Conduct feasibility testing using rigid tubing prototype.

Content:

Operation	Acceptance Criteria
Feed artery through rigid tubing	Artery end passes without snagging, tearing, or visible intimal abrasion.
Evert first artery end over tubing	Artery can be everted without tearing or overstretching. No spontaneous rolling back.
Pull opposing artery end over	The second artery can be pulled over the device with ease. The second artery does not roll back once secured on the device.
Add fluid flow through device	No leakage at implant site with added flow. Flow remains laminar or minimally disturbed.

The steps and acceptance criteria measured through the feasibility testing are summarized above in the table. The acceptance criteria was defined based on the design specifications for the final device. Ultimately this testing will confirm the stent concept compatibility with 2–5 mm arteries, smooth and safe manipulation, rapid procedural workflow, long-term patency, and the ability to withstand physiologic pressures up to 200 mmHg. The images presented below in Figures 13-16 were taken during implantation practice with the client on chicken arteries. The chicken arteries are very relevant to human arteries, and are used as vivo models for studying vascular biology [36]. The annotated images are attached to aid in the visual understanding of each image. Solid red lines indicate the tubing that is not covered by an artery. The dotted red line identifies the tubing that is behind or covered by an artery. The blue lines indicate the position of the artery relative to the rigid tubing. Lastly, black arrows represent the direction of fluid flow in our final step of testing.

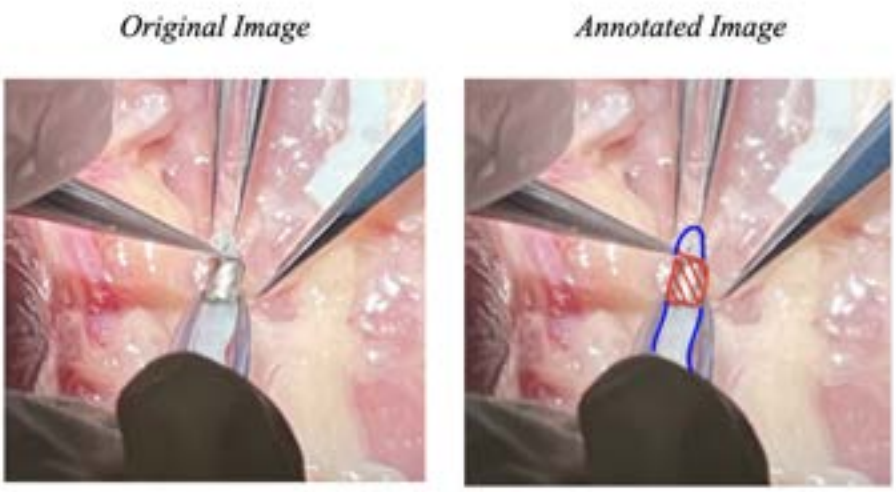

Figure 13: Image of artery being pulled through rigid tubing.

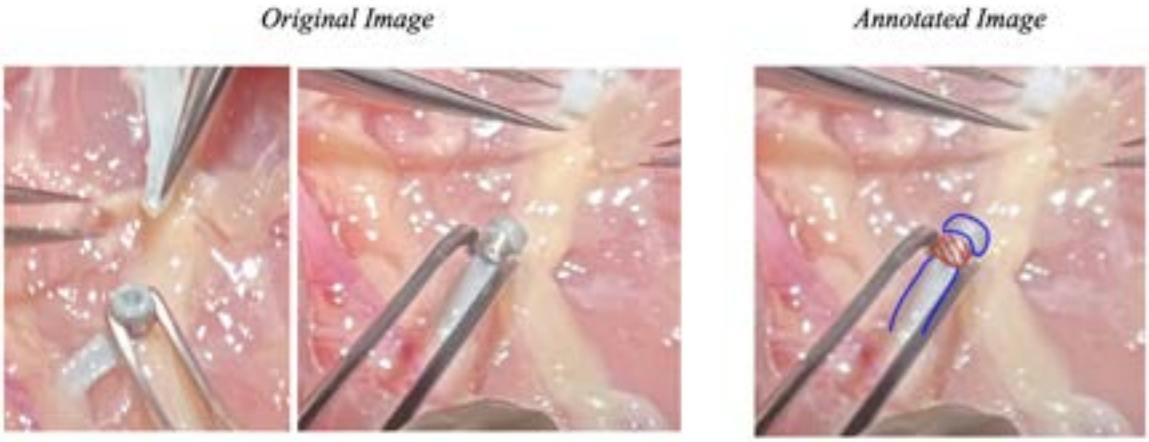

Figure 14: Image of first artery eversion.

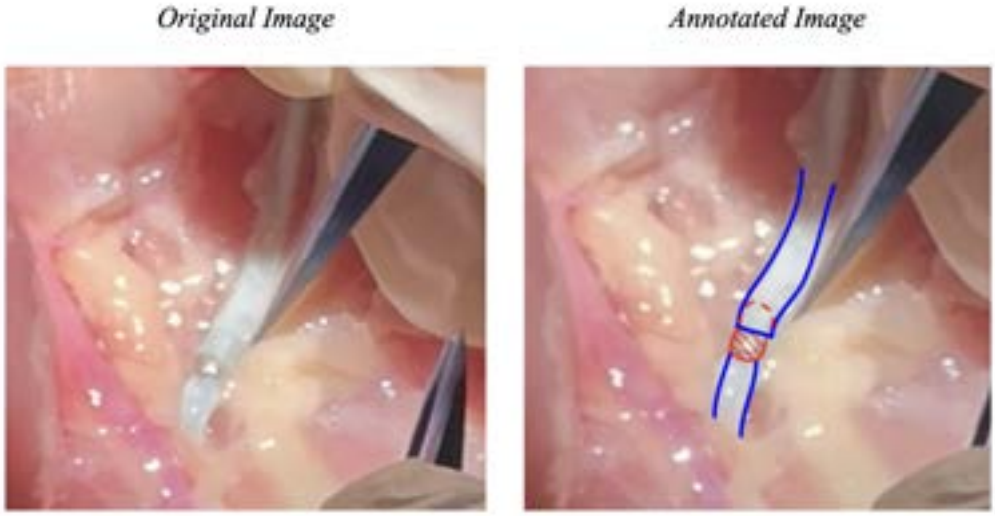

Figure 15: Images of opposing artery pulling over everted artery.

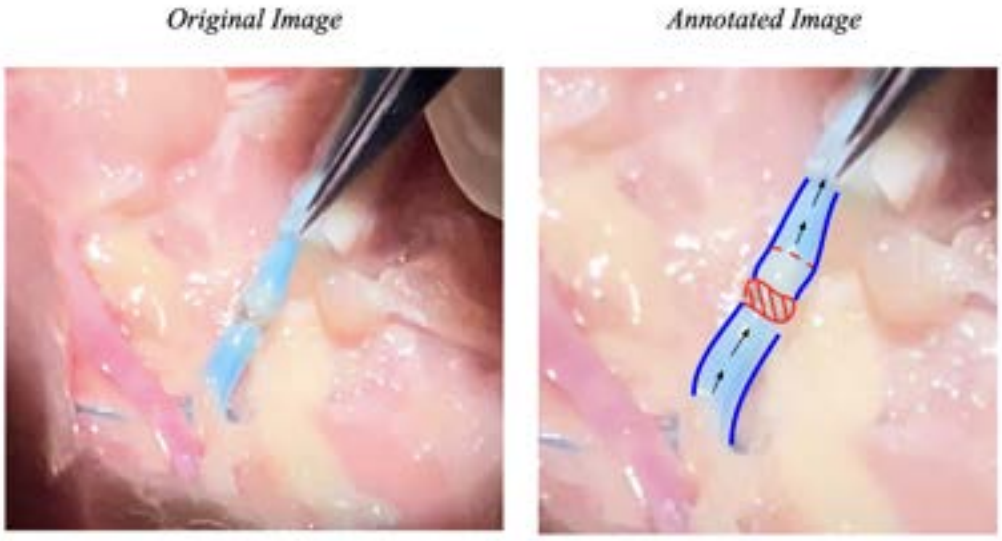

Figure 16: Images of fluid flow through the assembled device.

Conclusions/action items: Refer to this entry for information for testing as needed.

2025/09/18 - Arterial Coupler Re-Design Product Design Specification Attachment

ARSHIYA CHUGH - Dec 06, 2025, 4:59 PM CST

Title: Product Design Specification

Date: 9/18/25

Content by: Team

Present: Team

Goals: Create a comprehensive document outlining design specifications based on client request and preliminary research.

Content:

See attached below.

Conclusions/action items: Send to client for feedback. Continue design process. Meet as a team to discuss timeline.

ALLISON RAUSCH - Sep 22, 2025, 6:19 PM CDT

Download

Product_Design_Specification.pdf (509 kB)

2025/09/29 - Arterial Coupler Re-Design Preliminary Design Matrix Attachment

ARSHIYA CHUGH - Dec 06, 2025, 5:00 PM CST

Title: Preliminary Design Matrix

Date: 9/29/2025

Content by: Team

Present: Team

Goals: Determine criteria and their weight to score preliminary design ideas.

Content:

See PDF attached below.

Conclusions/action items: Continue to iterate design matrix through research and testing, send design matrix to client, prepare for preliminary presentations.

ALLISON RAUSCH - Sep 29, 2025, 4:10 PM CDT

Download

Design_Matrix.pdf (1.2 MB)

2025/10/03 - Arterial Coupler Re-Design Preliminary Design Presentation Powerpoint

ARSHIYA CHUGH - Dec 07, 2025, 2:30 PM CST

Title: Preliminary Design Presentation

Date: 10/3/2025

Content by: Team

Present: Team

Goals: Present preliminary design presentation to advising section.

Content:

See PDF attached below.

Conclusions/action items: Work on preliminary report with team. Meet with client to discuss materials order. Finalize final design and fabrication method.

ARSHIYA CHUGH - Dec 07, 2025, 2:29 PM CST

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Preliminary_Presentation.pdf (1.86 MB)

2025/10/08 - Arterial Coupler Re-Design Preliminary Report

ARSHIYA CHUGH - Dec 07, 2025, 2:36 PM CST

Title: Preliminary Design Report

Date: 10/8/25

Content by: Team

Present: Team

Goals: Compile a preliminary report for project and outline future fabrication and testing.

Content:

See PDF attached below.

Conclusions/action items: Work on preliminary fabrication and prototyping. Consult with client. Begin brainstorming testing ideas.

ARSHIYA CHUGH - Dec 07, 2025, 2:36 PM CST

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Arterial_Coupler_Re-Design__Preliminary_Report.pdf (4.71 MB)

2025/12/05 - Arterial Coupler Re-Design Final Poster Presentation Attachment

ARSHIYA CHUGH - Dec 07, 2025, 2:32 PM CST

Title: Final Poster Presentation

Date: 12/5/2025

Content by: Team

Present: Team

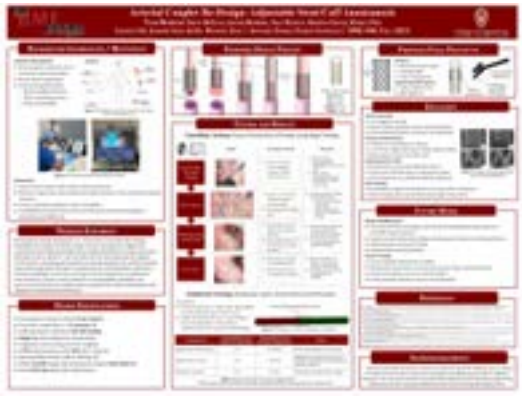
Goals: Present final poster presentation to highlight semester long progress.

Content:

See PDF attached below.

Conclusions/action items: Complete final deliverables. Update Lab Archives. Complete final report.

ARSHIYA CHUGH - Dec 07, 2025, 2:32 PM CST



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Final_Poster.pptx.pdf (2.42 MB)

2025/12/10 - Arterial Coupler Re-Design Report Final Report

SOFIA DECICCO - Dec 10, 2025, 2:31 PM CST

Title: Final Design Report

Date: 12/10/25

Content by: Team

Present: Team

Goals: Complete final report!

Content:

See PDF attached below.

Conclusions/action items: Start considering plans for next semester and project continuation!

SOFIA DECICCO - Dec 10, 2025, 2:30 PM CST

Download

Arterial_Coupler_Re-Design__Final_Report.pdf (13.6 MB)

2025/09/10 Arterial Haemodynamics

ALLISON RAUSCH - Sep 19, 2025, 6:46 PM CDT

Title: Arterial Haemodynamics

Date: 09/10/25

Content by: Ally

Present:

Goals: Understand the dynamics and physiology of arteries.

Content:

Purpose
- Aim is to provide a foundational understanding of arterial haemodynamics: how blood flows in arteries, how vessel wall properties and geometries affect flow, pressure, shear, etc.
- Useful for surgeons, engineers, and anyone developing vascular implants or interventions.

Basic Laws & Concepts
- Laplace's Law of Wall Tension: describes tension in the vessel wall in relation to internal pressure, radius, wall thickness. Helps understand how arteries endure pressure.
- Difference between **Newtonian** and **non-Newtonian fluids**: Blood does not behave strictly like a Newtonian fluid (its viscosity depends on shear rate, among other factors).
- Poiseuille's Law for laminar (steady) flow in cylindrical tubes; useful but limited because arteries have pulsatile and often non-ideal flow.
- Bernoulli's Equation for relating flow speed, pressure, and energy conservation in moving fluid.

Flow Patterns & Dynamics
- Laminar vs. Turbulent Flow: Reynolds number is introduced; small arteries + lower velocities tend to laminar flow; changes in geometry, high flow, or disturbances can provoke turbulence.
- Pulsatile Flow: Because the heart pumps in pulses, arterial flow is not steady; the pulsatility affects pressures, shear forces, wave reflections

Vessel Wall Properties
- Elasticity (Compliance): Arteries have elastic walls, composed of layers (elastin, collagen, etc.), which expand and recoil. This property influences how pressure waves propagate, how flow changes under pulsatile driving forces.
- Young's Modulus and wall thickness are relevant when modeling wall strain, expansion under pressure etc.

Pressure and Resistance Relations
- The analogy to electrical circuits: pressure difference analogous to voltage, flow to current, resistance to vascular resistance. Parallel and series arrangements help understand collaterals and branching.
- Resistance depends heavily on vessel radius (the fourth power in Poiseuille's law) and length, as well as fluid viscosity. Small changes in radius lead to large changes in resistance.

Shear Stress, Endothelial Interaction
- Wall Shear Stress (WSS): force per unit area exerted by flowing blood on the vessel wall. Both magnitude and spatial/temporal variation matter. Endothelial cells respond to WSS; low or oscillatory shear stress is associated with atherosclerosis

Wave Propagation
- When the heart generates a pressure pulse, this pulse travels through arteries. At junctions (bifurcations), changes in vessel properties, or at the periphery, waves are reflected; these reflected waves interact with incoming ones, affecting pressure, velocity waveforms.

Notes

- Mass conservation (continuity): flow in = flow out; cross-sectional area effects.
- Reynolds Number: indicator of whether flow is likely laminar or turbulent.

Modelling / Computation

- Use of computational models (CFD, fluid-structure interaction) to simulate flow in realistic geometries, with realistic boundary conditions.
- Trade-offs: including wall elasticity vs assuming rigid walls; non-Newtonian behaviour vs Newtonian simplifications; computational cost vs fidelity.

Practical / Clinical Implications

- Understanding haemodynamics helps in design of grafts, stents, vascular prostheses. e.g. matching mechanical compliance, avoiding regions of disturbed flow, preventing thrombosis, ensuring good endothelial health.

- Helps explain pathological changes: how atherosclerotic plaques tend to form in regions of low or oscillating shear; how stenoses alter flow, increase turbulence, change shear and pressure downstream, and how that leads to further disease.

Limitations / Simplifications Discussed

- Many models assume rigid walls or simple geometries, which may misestimate some parameters (pressure, flow speed, shear). Including wall compliance (elasticity) adds realism but more complexity.
- Steady flow assumptions are often violated in the pulsatile, variable environment of real arteries.
- Non-Newtonian properties of blood are ignored in simpler models; this can influence results, especially in small vessels or low shear rates.

Conclusions/action items: Understand these dynamics through the lens of microsurgery.

Citation:

[1] M. M. Lawence-Brown, K. Liffman, J. B. Semmens, and I. D. Sutalo, “Vascular Arterial Haemodynamics,” *Nih.gov*, 2025. https://www.ncbi.nlm.nih.gov/books/NBK534265/? (accessed Sep. 19, 2025).

https://www.ncbi.nlm.nih.gov/books/NBK534265/?

2025/09/11 Anastomotic Troubleshooting

ALLISON RAUSCH - Sep 22, 2025, 11:03 AM CDT

Title: Anastomotic Troubleshooting

Date: 09/11/2025

Content by: Ally

Present: N/A

Goals: Understand the risk factors that predispose to anastomotic leak

Content:

Importance of the Problem
- Anastomotic leak (AL) is a serious complication in colorectal surgery, associated with high morbidity and mortality.
- Leaks increase rate of organ dysfunction, readmissions, reoperations after elective colorectal resections.
- Surgeons' subjective assessment of anastomotic integrity at end of surgery is not very predictive of who actually leaks.

Risk Factors for Leak
- Three categories: patient factors, pathologic factors, technical factors
- Examples:

- Patient → Obesity; steroid use; high comorbidity (Charlson score); low lying tumor.
- Pathologic → Malignancy; preoperative radiation.
- Technical → Intraoperative transfusion; long operation time; poor perfusion; tension on low anastomoses

Low rectal (or low-lying) anastomoses carry higher risk; diversion (e.g., diverting loop ileostomy, DLI) might be considered in high risk cases

Intraoperative Assessment: Air Leak Test (ALT)
- Widely used to detect defects before closing surgery.
- Procedure: fill pelvis with saline, occlude upstream bowel, insufflate the bowel (via endoscope or syringe), look for bubbles escaping from anastomosis into the saline.
- Alternative methods: use of 60-cc syringe for insufflation; survey notes endoscope gives better visualization, less risk of missing leaks or causing barotrauma.

Evidence for ALT
- Studies show ALT reduces rates of clinical leaks (CL) and radiologic leaks (RL). like Beard et al.: among ALT group vs non-ALT, fewer leaks, and intraoperative detection & repair significantly lowered postoperative leak rate.
- Other studies: Allaix et al. in left-sided colon resections; Ricciardi et al.; all show ALT is associated with improved outcomes.

Managing a Positive ALT
- If leak is detected in ALT: options are:

1. Oversew the defect (suture the defect) → then repeat ALT to check repair.
2. Diverting loop ileostomy (DLI) alone or with oversewing
3. Redo the anastomosis: resect faulty parts, make fresh ends (stapled or handsewn), then test again. This can be difficult in very low rectal anastomoses due to limited length.

Technical Problems with Circular Staplers
- Circular staplers are common for colorectal anastomoses; but about 20% rate of technical error reported in some series.
- Types of technical problems:

- Stapler misfire → Device fails to perform both cutting & stapling properly; might cut but not staple, or get stuck. Needs correction.

- Incomplete donuts → The rings (“doughnuts” of tissue removed by stapler) are incomplete → this suggests compromised anastomosis; associated with positive ALT
- Staple-line Bleeding → Bleeding from cut edge, often intraluminal; may require hemoclips, transanal techniques, or redo if tissue not stapled

Morphologic Characteristics of Doughnuts

- Researchers have studied whether features of the removed doughnuts (after circular stapler use) predict leaks. One finding: minimal height of colonic doughnut <4.5 mm has higher odds of CL (around OR = 5.74) compared to ≥ 4.5 mm.
- But measuring these features intraoperatively is not yet standard; more data needed.

Stapler Misfire & Device Failures

- Misfire types include: cutting without stapling; failure to disengage; failure of staple deployment; or failure of the device to release properly.

- Methods to address misfire or stuck devices: slow rotation, gentle advancement; disconnecting handle; possibly transanal endoscopic or minimally invasive rescue. ALT still needed after fixes.

Bleeding Along Staple Line

- Can occur when staples don’t fire properly or anticoagulation; it’s intraluminal most often.
- Surgeons can visualize via flexible sigmoidoscope during ALT; control with clips, transanal techniques. If staple failure (no staples), may need to redo anastomosis

Conclusions/action items: - All new colorectal anastomoses should be tested intraoperatively (e.g. ALT) to catch acute technical defects.
- Negative ALT doesn’t absolutely guarantee no leak later, but many leaks can be prevented by addressing issues found intraoperatively
- Surgeons using circular staplers need good technique and awareness of device-specific failure modes.

Citation:

[1] N. M. Sell and T. D. Francone, “Anastomotic Troubleshooting,” *Clinics in Colon and Rectal Surgery*, vol. 34, no. 06, pp. 385–390, Nov. 2021, doi: https://doi.org/10.1055/s-0041-1735269.

https://pmc.ncbi.nlm.nih.gov/articles/PMC8610636/

2025/09/11 Arterial Anastomosis in Animal Models

ALLISON RAUSCH - Sep 22, 2025, 11:11 AM CDT

Title: Arterial Anastomosis in Animal Models

Date: 09/11/2025

Content by: Ally

Present:

Goals: understand how vessel caliber growth and long-term flow preservation occur after arterial anastomosis in young versus adult models, in order to inform recoupler device design that accommodates both pediatric and adult vascular environments

Content:

Purpose

- To examine how arterial micro-anastomoses behave over time in young vs adult rats when sewn with a continuous suture technique.

- Specifically, to evaluate whether the caliber (inner diameter) of the vessel at the anastomosis grows in proportion in young animals, and to check late morphological changes and distal blood flow.

Methods

- 74 Wistar rats: 44 adults, 30 young.
Each underwent microsurgical end-to-end anastomosis of the abdominal aorta using continuous - 10-0 polypropylene sutures.
- Baseline measurements taken (vessel diameter, blood flow) before surgery; then follow-up at 6 months up to 1 year post-surgery, with remeasurement of diameter, blood flow, and evaluation for complications (thrombosis, stenosis, aneurysm).

Results

- Mortality: ~31.8% in adult rats, ~13.3% in young rats over the period.
- Vessel diameter growth: Adult rats showed ~13.3% increase in aortic caliber at the anastomosis; young rats showed ~25% increase.
- Blood flow distal to the anastomosis remained about the same pre- and post- surgery in both young and adult rats; no significant worsening in flow despite the changes in size.
- Complications: some animals developed thrombosis, stenosis, or aneurysm. Rates of these complications were not statistically much different between young vs adult in this study.
- Observed collateral circulation in animals when there was stenosis or thrombosis, which mitigated severe functional deficits

Interpretation / Implications

- Continuous suturing technique does not prevent growth of vessel at anastomotic site in growing (young) animals, which is important from a pediatric microsurgery/transplantation perspective.
- The occasional development of aneurysm or stenosis underscores that while the technique allows growth, it is not risk-free. Careful long-term follow-up is needed.

Conclusions/action items: The study shows that continuous sutured anastomoses allow proportional vessel growth with maintained blood flow in young rats, suggesting that an ideal recoupler should similarly permit growth at the anastomotic site while minimizing risks of stenosis, thrombosis, or aneurysm

Citation:

[1] M. M. Santos, A. Cristina, A. V. Lacerda, J. de, R. Schlaich, and Uenis Tannuri, “Microsurgical arterial anastomosis in young and adult rats: an evolutive and comparative study,” *Acta Cirúrgica Brasileira*, vol. 37, no. 6, Jan. 2022, doi: https://doi.org/10.1590/acb370604.

https://pmc.ncbi.nlm.nih.gov/articles/PMC9448246/

2025/09/13 Wall Shear Stress

ALLISON RAUSCH - Sep 22, 2025, 11:37 AM CDT

Title: Wall Shear Stress

Date: 09/13/2025

Content by: Ally

Present:

Goals: Understand the vessel mechanics in arterial anastomoses.

Content:

Problem

- Prosthetic infrainguinal bypass grafts commonly fail due to myointimal hyperplasia (MIH), often concentrated at the heel and toe of the graft-artery anastomosis.
- It has been observed that using an interposition vein cuff (IVC) between the prosthetic graft and the distal (recipient) artery improves patency (i.e. fewer graft failures). The mechanism is thought to involve altering the mechanical/hemodynamic environment at the anastomosis.

Objective

- To determine whether the IVC changes wall shear stress (WSS) magnitude and distribution in the recipient artery compared to a conventional end-to-side (ETS) anastomosis. The hypothesis is that the IVC redistributes WSS so that regions prone to low WSS (which are associated with MIH) are reduced or removed, especially at the heel.

Methods

- Created life-size physical models of two scenarios: (a) conventional end-to-side (ETS) anastomosis, (b) ETS + interposition vein cuff (IVC).

Flow was pulsatile, simulating physiologic conditions. Measurement via two-component laser Doppler anemometry. Velocity vectors measured in the symmetry plane of anastomosis; near-wall velocities on the floor and upper wall of recipient artery; from those, WSS estimated.

Results

- In ETS anastomosis:
  - Flow separation occurs at the graft hood.
  - Strong radial velocity at the heel.
  - A stagnation point (a point where velocity is very low / zero) on the floor of the recipient artery that moves slightly over the cardiac cycle. Low WSS regions appear at both the heel and across the floor.

- In IVC + ETS:

- A coherent vortex forms in the vein cuff volume, particularly during systolic deceleration through diastole. The vortex occupies most of the cuff.
  - The stagnation point on the floor is still present but oscillates over a smaller region (~4 mm) over the cardiac cycle.
  - Low mean WSS (< 0.5 N/m²) zones:
    -In ETS, these zones are found at the heel and the floor of the recipient artery.
    -In IVC, low-WSS is found only on the floor; importantly, the heel (which is often a site for MIH) no longer has that low shear region. Also, the area of low WSS is generally smaller / less extensive.

Implications

- Hemodynamic factors (especially low WSS) are likely central in the development of intimal hyperplasia. If you can mitigate or redistribute low shear zones, you may reduce MIH and improve long-term patency.
- The geometry of the anastomosis and any adjunct (like the cuff) matter: how flow enters, how disturbances or separations occur, where stagnation happens, etc. These are key in design.

Project:

- Design your device so it minimizes or removes regions of low wall shear stress, especially at “heel” locations (i.e. points of flow impingement or graft-to-native vessel transition).
- Possibly include features analogous to a “cuff” or flow diverter geometry that can smooth or redirect flow, prevent flow separation, reduce stagnation.
- Evaluate how flow vortices may help or harm (they could reduce areas of low shear if appropriately located, but could also create turbulence or energy loss).
- Use physical or computational models to map WSS distributions in your designs: compare conventional pledgeted / sutured anastomoses vs your recoupler geometry vs perhaps modified cuff structures
- Pay attention to dynamic behavior (over pulsatile cycle): not just instantaneous flow, but how stagnation points and low-shear zones shift over time.

Conclusions/action items: The interposition vein cuff changes wall shear stress distribution: specifically, it removes the low WSS region at the heel of the artery, which may explain the clinical observation that MIH is often redistributed away from heel (i.e., the problem site) in grafts using IVC.

Citation:

[1]T. V. How, C. S. Rowe, G. L. Gilling-Smith, and P. L. Harris, “Interposition vein cuff anastomosis alters wall shear stress distribution in the recipient artery,” *Journal of Vascular Surgery*, vol. 31, no. 5, pp. 1008–1017, May 2000, doi: https://doi.org/10.1067/mva.2000.105961.

https://www.jvascsurg.org/article/S0741-5214(00)86121-2/fulltext

2025/09/15 Technical Case Study for Emergency Anastomosis

ALLISON RAUSCH - Sep 22, 2025, 11:42 AM CDT

Title: Technical Case Study for Emergency Anastomosis

Date: 09/15/2025

Content by: Ally

Present:

Goals: Learn from this rapid continuous-suture anastomosis technique what elements (posterior wall visualization, flushing before final closure, minimal tension) are essential so that a recoupler can replicate those in a device-based format to reduce operative time but maintain safety

Content:

Context
- Patient: 22-year-old male with a transected superficial femoral artery from a gunshot wound.
- Injury required resection of injured arterial segment and then repair via end-to-end anastomosis.

Technique Used
- Suture material: non-absorbable monofilament polypropylene, 6-0, on an atraumatic needle.
- Suturing method: *continuous suture* (two-armed) with perpendicular bites placed ~1 mm from vessel edge, ~1 mm apart.
- Starting point: begin at position opposite the operator (3 or 9 o'clock, depending on which side), placing first two bites from inside to outside on both ends of the vessel; tie those first. Then proceed with posterior wall suture line, then anterior wall.
- Flushing: before completing the anterior row, flush vessel of debris and air via sequential proximal and distal clamp release/re-clamping; flush lumen with heparinized saline. Remove distal clamp before final knot to avoid air entrapment.

Advantages
- The "operating system" is always oriented toward the surgeon — meaning that the surgeon has good visibility of the posterior wall when placing posterior sutures because ends are mobilized/visualized, avoiding traction stitches that might obscure the view.
- Rapid and reliable. Particularly useful in emergency trauma, where speed matters.
- Flushing prior to final rows helps prevent complications (air embolism, debris, thrombosis) and helps ensure patency.

Outcomes
- The repair was successful: post-operative recovery, return of distal pulses, discharge home on post-op day 3 with normal extremity function.

- No complications were reported in this particular case.

Technique details with potential limits
- Vessel mobilization: needed to ensure ends can be approximated without tension. Tension is avoided.
- The method is simple and depends heavily on the surgeon's ability to see the posterior wall and orient the vessel ends well. Thus visibility / access matters.
- It's a single case report → low sample size, limited generalizability. Not enough data on how it performs under challenging conditions (small vessels, less accessible anatomy, or with adverse patient factors).

Project:

- Speed & simplicity matter, especially in trauma / emergency settings. A device (recoupler) that reduces time and simplifies steps (visualization, suturing) could offer real benefit.
- Flushing & prevention of air / debris / thrombosis is critical. Any device must allow or integrate flushing before final sealing / coupling to avoid emboli or clot formation.
- Good posterior wall exposure: devices that hide or obscure the back wall (or require work "blindly") can introduce risk. Your recoupler should either provide built-in alignment or ensure full wall access / accurate apposition.

- Continuous vs interrupted sutures: continuous has advantages in speed, but might have risk trade-offs (e.g. tension distribution). For recoupler, think about how sealing is achieved (continuous seal, ring, clip, etc.), and how it handles the stress across the seam.
- Tension-free anastomosis: critical to avoid mechanical failure, mismatch, or leak. Device must accommodate some movement and be dimensioned / deployed to avoid tension.
- Air or fossilized risk mitigation: devices need ways to flush or purge air before full sealing.

Conclusions/action items: This case report shows that a simple, continuous, well-oriented suture technique with careful flushing can achieve excellent outcomes in emergency arterial repair, implying that a recoupler device should aim to provide similar control, exposure, and flushing capability to match or exceed this standard

Citation:

[1] C. G. Ball and D. V. Feliciano, “A simple and rapid vascular anastomosis for emergency surgery: a technical case report,” *World Journal of Emergency Surgery : WJES*, vol. 4, p. 30, Aug. 2009, doi: https://doi.org/10.1186/1749-7922-4-30.

https://pmc.ncbi.nlm.nih.gov/articles/PMC2727494/

2025/09/20 Arterial Anastomosis Applications

ALLISON RAUSCH - Oct 01, 2025, 10:42 AM CDT

Title: Arterial Anastomosis Applications

Date: 09/20/2025

Content by: Ally

Present: N/A

Goals: Find out how impactful arterial anastomosis improvement is.

Content:

Anastomosis:

- Surgical procedure used to connect blood vessels to each other.
- Can involve natural vessels or artificial conduits.

Procedures that require vascular anastomosis

- Coronary artery bypass surgery (CABG) → reconnects blood supply to the heart.
- Artery-to-vein connection for hemodialysis access.
- Aneurysmectomy (removal of aneurysm).
- Repair of damaged arteries (e.g., trauma such as gunshot wound).
- Solid organ transplants → connecting donor organ vessels to host blood supply.

What to Expect in Surgery

- Blocked section of vessel is bypassed using either:
    - A natural conduit (such as vein from patient's leg).
    - An artificial conduit (man-made tube).
- Ends of vessel and conduit are sutured together.

Risks of Vascular Anastomosis

- **Most serious risk**: Anastomotic leak
    - Symptoms: fever, infection, abdominal pain, diarrhea, low urine output.
- Higher-risk patients: obese, on steroids, excessive alcohol use.
- Other complications:
    - Blood clots → pulmonary embolism, DVT, heart attack.
    - Severe bleeding.
    - Scarring.
    - Blockage in another vessel.
    - Infection leading to sepsis.
    - Damage to surrounding vessels.
- Importance of early detection: small leaks may be treatable with antibiotics.

Conclusions/action items: Continue research on the subject

Citation:

https://www.mercy.com/health-care-services/heart-vascular/treatments/vascular-anastomosis

[1] “Vascular Anastomosis | Heart and Vascular Care | Mercy Health,” *www.mercy.com*. https://www.mercy.com/health-care-services/heart-vascular/treatments/vascular-anastomosis

2025/10/1 Procedures Using Arterial Anastomoses

ALLISON RAUSCH - Oct 01, 2025, 10:38 AM CDT

Title:

Date:

Content by:

Present:

Goals: Find how many/ what kind of procedures arterial anastomoses are used in.

Content:

Source 1: https://my.clevelandclinic.org/health/treatments/24035-anastomosis

Anastomoses in general - not just arterial

- **Vascular / circulatory system** (connecting blood vessels — arteries or veins)
    - Arterial bypass surgery (peripheral or coronary artery bypass graft)
    - Dialysis access surgery (arteriovenous fistula creation)
    - Organ transplantation (connecting donor organ vessels to recipient circulation)
- **Gastrointestinal / digestive tract**
    - Bowel resection (reconnecting small or large intestine ends)
    - Ileocolonic anastomosis (connecting ileum to colon)
    - Ileal pouch–anal anastomosis (after proctocolectomy)
    - Gastric / intestinal bypass (e.g. weight loss surgery)
- **Genitourinary tract / urinary system**
    - Urethra to bladder reconnection (bladder neck or urethral surgery)
    - Other urinary tract surgeries requiring tubular reconnection

All in all:

- **Coronary Artery Bypass Grafting (CABG)**
    - One of the most common surgeries involving arterial anastomoses. In the U.S., nearly **400,000 CABG procedures** are performed annually. [3]
    - The operation rewires coronary arteries by grafting arteries or veins from elsewhere in the body to restore blood flow past a blockage. [2]
- **Peripheral Vascular Bypass / Revascularization**
    - Surgical bypass of occluded segments in peripheral arteries (leg, arm) is common in peripheral artery disease (PAD). [7]
    - For example, lower-extremity vascular procedures have been increasing in incidence, indicating substantial clinical demand.
- **Microsurgical (Free Flap) Reconstruction**
    - In reconstructive surgery (like in head/neck, breast, limbs), small arteries (2–5 mm) are reconnected (anastomosed) to supply blood to tissue flaps.
    - One systematic review of arterial coupler use reports an **overall success rate of ~92.1%** (617 of 670) in arterial anastomoses attempted with a coupler device. [5]

- **Digital / Micro-artery Anastomoses**
    - In microsurgery, small digital arteries (in fingers) may undergo end-to-end or end-to-side arterial anastomosis. A recent study observed **no significant difference** in outcomes between ETE and ETS on digital arteries in free flap reconstructions. [6]
- **Congenital Heart / Pediatric Procedures**
    - The **arterial switch operation** (Jatene procedure) for transposition of the great arteries involves reconnecting the pulmonary and aortic arteries. [4]
    - Other cardiac bypass operations often involve small arterial reconnections (like grafting or reimplanting coronary arteries).

Conclusions/action items: Add to the impact section of the prelim presentation.

Citations:

[1] Cleveland Clinic. “Anastomosis: Definition, Types & Procedure.” *Cleveland Clinic*, 8 Sept. 2022, my.clevelandclinic.org/health/treatments/24035-anastomosis.

[2] “Coronary Artery Bypass Grafting (CABG) FAQs | Frankel Cardiovascular Center | Michigan Medicine.” *Umcvc.org*, 2023, www.umcvc.org/conditions-treatments/coronary-artery-bypass-grafting-cabg-faqs? Accessed 1 Oct. 2025.

[3] Ghandakly, Elizabeth C, et al. “Coronary Artery Surgery: Past, Present, and Future.” *Rambam Maimonides Medical Journal*, vol. 15, no. 1, 19 Jan. 2024, pp. e0001–e0001, www.ncbi.nlm.nih.gov/pmc/articles/PMC10807854/, https://doi.org/10.5041/rmmj.10515. Accessed 3 Apr. 2024.

[4] Losay, Jean, et al. “Late Outcome after Arterial Switch Operation for Transposition of the Great Arteries.” *Circulation*, vol. 104, no. suppl 1, 1 Mar. 2002, pp. I–126, https://doi.org/10.1161/hc37t1.094716. Accessed 21 Apr. 2023.

[5] Pafitanis, Georgios, et al. “Microvascular Anastomotic Arterial Coupling: A Systematic Review.” *Journal of Plastic, Reconstructive & Aesthetic Surgery*, vol. 74, no. 6, June 2021, pp. 1286–1302, https://doi.org/10.1016/j.bjps.2020.12.090. Accessed 19 Dec. 2021.

[6] Troisi, Luigi, et al. “End-To-Side Anastomosis on Digital Arteries: Just a Technical Choice or a Real Benefit?” *Plastic & Reconstructive Surgery Global Open*, vol. 10, no. 9, 1 Sept. 2022, pp. e4535–e4535, journals.lww.com/prsgo/fulltext/2022/09000/end_to_side_anastomosis_on_digital_arteries__just.44.aspx?utm_source=chatgpt.com, https://doi.org/10.1097/gox.0000000000004535. Accessed 1 Oct. 2025.

[7] Young, Jacob, et al. “Peripheral Vascular Bypass.” *Nih.gov*, StatPearls Publishing, 14 Aug. 2023, www.ncbi.nlm.nih.gov/books/NBK499827/? Accessed 1 Oct. 2025.

2025/10/05 Nitinol Properties

ALLISON RAUSCH - Dec 09, 2025, 7:41 PM CST

Title: Nitinol Properties

Date: 10/05/2025

Content by: Ally

Present: Ally

Goals: Figure out if nitinol is a material we could proceed with

Content:

Nitinol Wire

- Nitinol wire is an alloy of nickel and titanium that can return to its original shape when heated to its transformation temperature.
- Its shape-memory and malleable characteristics make it highly valuable for designing medical devices.

Key Properties

- Shape-memory (returns to pre-defined shape after deformation + heating)
- Excellent thermal conductivity
- Corrosion-resistant
- Biocompatible
- High ultimate tensile strength — durable even under repeated deformation and heat cycles.

Medical Applications

- Devices for minimally invasive surgery, such as flexible endoscopic tools: Nitinol wire can be flexible for navigation and then become rigid when needed.
- Implants — due to biocompatibility and corrosion resistance, used in permanent implants.
- Stents and catheters — Nitinol's properties make it ideal for expandable stents and flexible catheter shafts.
- Orthodontic devices, such as braces/archwires — using shape-memory to apply consistent force as teeth move.
- Surgical instruments — instruments might utilize Nitinol for flexibility + strength, especially where deformation and recovery are needed.

Industrial / Other Applications

- Springs, actuators, and sensors — taking advantage of shape-memory for self-adjusting or self-fitting mechanisms.
- Items like eyeglass frames or self-fitting products, where flexibility + shape-memory offer practical benefits.
- Aerospace, robotics, and other advanced fields — Nitinol used where strength, shape-memory, and corrosion resistance are advantageous.

Manufacturing

- The basic materials (nickel and titanium) are melted to form the alloy; proportions can be adjusted to create Nitinol with different characteristics.
- A heat-treatment process is crucial to "activate" the shape-memory property — the heating and controlled cooling influence final behavior.
- For many applications, Nitinol wire is combined with other materials (e.g. non-shape-memory steel wires) to form cables or reinforced assemblies, increasing strength and durability for repeated use.

Future Work

- There is continuing research into refining production and processing techniques to improve performance and reliability of Nitinol wire
- Potential future applications include “smart” materials for robotics or adaptive devices that respond to stimuli like temperature or pressure, expanding Nitinol’s use beyond just medical or industrial devices.

Conclusions/action items: Do further research and potentially proceed with nitinol.

Citation:

[1] “Nitinol: Properties, Applications, and Uses | Seisa Medical,” *https://seisa.com/*. https://seisa.com/nitinol-wire-properties-applications-and-uses/

2025/10/20 Nitinol Applications in Medicine

ALLISON RAUSCH - Dec 09, 2025, 7:37 PM CST

Title: Nitinol Applications In Medicine

Date: 10/20/2025

Content by: Ally

Present: Ally

Goals: Find out how nitinol is used in medical devices

Content:

General Properties:

- nickel–titanium alloy with unique shape-memory and superelastic properties
- biocompatible, corrosion-resistant, and highly fatigue-resistant.
- Especially useful for minimally invasive medical devices that must deform and recover repeatedly inside the body.

1. Stents

- Nitinol stents can be compressed for catheter delivery and then self-expand once inside the blood vessel.
- They maintain vessel patency (keep vessels open) better than many balloon-expandable stents.
- One reported 12-month patency rate is 83.2% for Nitinol stents vs ~64.8% for non-Nitinol stents.

2. Guidewires

- Nitinol guidewires are flexible, kink-resistant, and easily maneuverable.
- They are commonly used in minimally invasive vascular procedures such as angioplasty.
- Compared to stainless steel, they reduce procedural complications due to better flexibility and torque control.

3. Orthodontic Archwires

- Nitinol archwires provide continuous, gentle force for tooth movement.
- Shape-memory allows the wire to return to its original shape as teeth shift.
- Studies show about 30% faster alignment in the first six months compared to stainless steel wires.

4. Endovascular Clot Retrieval Devices

- Nitinol is used in stent-retriever devices for removing blood clots in stroke patients.
- The device expands inside the vessel, captures the clot, and allows extraction.
- One study reported ~49% functional independence at 90 days versus ~13% with standard treatment alone.

5. Heart Valve Frames

- Nitinol is used in transcatheter heart valve replacement (TAVR) frames.
- The frame allows the valve to be collapsed for catheter delivery and then expand in the heart.
- One-year mortality for Nitinol-based transcatheter valves was reported at ~1.0% vs ~2.5% for open-heart surgery.

6. Bone Fixation and Orthopedic Implants

- Nitinol is used in bone staples, plates, and intramedullary implants.

- Shape-memory enables continuous compression at fracture sites.
- In ankle fracture repair, Nitinol staples showed ~40% faster healing than traditional titanium fixation.

Overall Impact

- Nitinol enables smaller incisions, faster recovery, and improved patient outcomes.
- Its mechanical adaptability allows it to function in dynamic biological environments.
- It is now a cornerstone material in cardiovascular, dental, neurological, and orthopedic devices.

Conclusions/action items: look into material properties in vivo further

Citation:

[1] “Top 6 Medical Applications of Nitinol,” *Samaterials.com*, 2025. https://www.samaterials.com/content/top-6-medical-applications-of-nitinol.html

2025/11/03 Stent Geometry

ALLISON RAUSCH - Dec 09, 2025, 7:46 PM CST

Title: Stent Geometry

Date: 11/03/2025

Content by: Ally

Present: NA

Goals: Figure out the effects of stent geometries on hemodynamics

Content:

- This study investigated how different stent geometries affect both mechanical stress and blood flow behavior after implantation in a curved, stenotic coronary artery.
- The goal was to understand how stent structure influences arterial stress, plaque stress, and post-stenting hemodynamics, which are linked to restenosis and thrombosis.

Stent Designs Studied

- Three commercially based stents:
    - Palmaz-Schatz-shaped (PS-shaped)
    - Xience Prime-shaped (XP-shaped)
    - Cypher-shaped (C-shaped)
- Three modified versions of the C-shaped stent designed by the authors:
    - C-Rlink (reduced number of links)
    - C-Rcrown (reduced number of strut crowns)
    - C-Astrut (aligned struts with peak-to-peak connections)
- All stents had the same material properties, length, strut thickness, and crimped diameter so that differences were due only to geometry.

Methods

- Finite Element Analysis (FEA) was used to simulate balloon-expanded stent deployment inside a curved, stenotic artery with plaque.
- After deployment, the deformed artery geometry was used to perform Computational Fluid Dynamics (CFD) simulations.
- Hemodynamic parameters analyzed included:
    - Wall shear stress (WSS)
    - Time-averaged wall shear stress (TAWSS)
    - Oscillatory shear index (OSI)
- Structural parameters analyzed included:
    - Stent recoil
    - Plastic strain
    - Von Mises stress in plaque and arterial wall

Key Structural (Mechanical) Results

- The PS-shaped stent showed:
    - The smallest recoil

    - The largest diameter expansion
    - The highest plastic strain, indicating strong structural expansion
- However, the PS-shaped stent also produced the highest von Mises stress in the plaque and arterial wall.
- Compared to the original C-shaped design:
    - C-Rcrown and C-Astrut showed reduced recoil
    - Larger diameter expansion
    - Improved overall mechanical performance

Key Hemodynamic Results

- The PS-shaped stent produced:
    - The smallest regions of low WSS and low TAWSS
    - Smaller regions of high OSI
    - These flow patterns are considered more favorable for vascular healing
- C-Rcrown and C-Astrut also showed:
    - Reduced low-WSS regions
    - Improved flow patterns compared to the original C-shaped stent
- C-Rcrown specifically showed a reduction in high OSI area, indicating less oscillatory and disturbed flow.

Conclusions/action items:

- Stent structural geometry strongly influences both mechanical behavior and blood-flow patterns after implantation.
- While PS-shaped stents perform well mechanically and hemodynamically, they also impose higher stress on the vessel wall, which may increase injury risk.
- Optimized designs such as C-Rcrown and C-Astrut improve both structural stability and blood-flow conditions compared to traditional C-shaped stents.
- Combined FEA + CFD modeling in realistic curved arteries provides a more accurate method for evaluating stent performance and guiding future stent design.

Citation:

[1] L. Wei, H. L. Leo, Q. Chen, and Z. Li, “Structural and Hemodynamic Analyses of Different Stent Structures in Curved and Stenotic Coronary Artery,” *Frontiers in Bioengineering and Biotechnology*, vol. 7, Dec. 2019, doi: https://doi.org/10.3389/fbioe.2019.00366.

2025/09/10 3D Printed Sugar Based Stents

ALLISON RAUSCH - Sep 19, 2025, 6:40 PM CDT

Title: 3D Printed Sugar Based Stents

Date: 09/10/2025

Content by: Ally

Present: N/A

Goals: Learn about an existing/potential competing design for arterial anastomosis

Content:

Problem / Motivation

- Microvascular anastomosis (suturing very small blood vessels) is common in reconstructive and transplant surgeries, but is technically difficult and time-consuming, especially for arteries.
- Existing coupling or clamp-type devices are more suitable for veins; arteries usually require sutures which slow down procedures and can risk errors.

Proposed Solution

- The authors propose a dissolvable sugar-based stent that temporarily holds vessel ends in place during suturing, then dissolves once blood flow is restored.
- Use of 3D printing to produce stents with custom geometries and sizes so they can match different vessel dimensions. This allows tailoring to patient needs.

Composition

- The stent ink / material is composed of sucrose, glucose, dextran (as a plasticizer to reduce brittleness), and sodium citrate (to reduce risk of blood clotting, i.e. thrombosis).
- Dextran improves flexibility and mechanical resilience.

Mechanical/Functional Properties

- Mechanical strength is sufficient: the engineered sugar-based stents can withstand the stresses of suturing without breaking. They are non-brittle (they deform rather than shatter).
- Elastic modulus measured was about 16 ± 2.3 MPa, which is higher than typical values for arteries (~1.5 MPa) and veins (~3.1 MPa). This suggests they are stiff enough to support the vessels but not overly rigid.

Tailorable Dissolution / Timing

- The dissolution (i.e., how fast the stent dissolves once exposed to flow) can be tuned between roughly 4-8 minutes depending on thickness and geometry.
- In ex vivo tests under PBS (phosphate buffered saline) flow, stents gradually dissolved in that time frame; no large fragments were left (important to avoid embolization or blockage).

Biocompatibility

- The composition (including sodium citrate) reduces thrombogenicity (tendency to clot). Blood-clotting time assays indicated low risk.

- Tests with endothelial cells (human umbilical vein endothelial cells, HUVECs) show high cellular viability after exposure to dissolved stent components, including under flow conditions.

Ex Vivo Performance & Suturing Time

- Tested on pig arteries ex vivo: using the stent reduced the time for suturing anastomosis from about 15 minutes (conventional technique) to around 5 minutes with stent assist.
- No leaks were observed during or after suturing when the stents were in place and then dissolved under perfusion.

Printability & Practicality

- The sugar glass mixture can be prepared and 3D printed fairly quickly (material preparation and printing) — possibly in the operating room.
- The printing process is extrusion-based; parameters like nozzle diameter, printing speed, and pressure affect resolution.

Future Directions?

- Testing in live animal models to verify in vivo safety and effectiveness.
- Possibility of using stents to facilitate suture-free anastomosis (e.g. with surgical glues), since the stent could help prevent glue leakage into the vessel.

Conclusions/action items: Research how feasible this design is and how it could realistically compete with or inspire our direction.

Citation:

[1] A. Farzin *et al.*, “3D-Printed Sugar-Based Stents Facilitating Vascular Anastomosis,” *Advanced Healthcare Materials*, vol. 7, no. 24, Oct. 2018, doi: https://doi.org/10.1002/adhm.201800702.

https://pmc.ncbi.nlm.nih.gov/articles/PMC6394876/

2025/09/11 Sutureless Approaches to Anastomosis

ALLISON RAUSCH - Sep 22, 2025, 11:17 AM CDT

Title: Sutureless Approaches to Vascular Anastomosis

Date: 09/11/2025

Content by: Ally

Present:

Goals: To extract from existing sutureless vascular-anastomosis technologies their successful design elements and failure modes in order to guide the development of a recoupler that can reliably perform arterial anastomosis with minimal injury, thrombosis risk, and maximal long-term patency

Content:

Purpose

- Review of sutureless vascular anastomotic techniques — both those FDA-approved and those under investigation.
- Compare different classes of devices / techniques: extraluminal couplers, intraluminal devices, tissue adhesives, laser/vacuum-assisted methods.
- Analyze criteria important for artery compatibility: risk of intimal damage, thrombosis, restenosis, deployment/maintenance complications.

Definitions

- Advantages vs traditional sutures: faster operation, less ischemic time, potentially lower cost and required skill level.
- Challenges especially acute when applied to arterial anastomoses rather than venous. Arteries have higher pressure, more elastic walls, thicker media

Existing Devices & Methods

- Extraluminal couplers: GEM / GEM flow coupler is FDA-approved; mostly for veins and some arteries under limited conditions.
- Intraluminal devices: fewer available; some in preclinical stages. These are immersed inside the lumen; risk vs benefit tradeoffs differ.
- Tissue adhesives / sealants: adhesives that bond vessel ends without full mechanical coupling or suturing. Useful in some contexts; concerns include durability, compliance mismatch, risk of leak or adhesive failure.

Material & Biomechanical Considerations

- Material composition matters: adhesives or devices must be biocompatible, resist thrombosis, minimize intimal trauma.
- Need to match mechanical properties (compliance, flexibility) to native artery to avoid stress concentrations, turbulence, intimal hyperplasia.

Failure Modes / Risks

- Intimal damage: devices that require eversion or clamps, or that generate sharp edges/pressure points, risk injuring intima.
- Thrombosis: exposure of non-native surfaces, flow disturbances, material toxicity etc.

- Restenosis: due to mechanical mismatch, chronic inflammation, cell proliferation.
- Deployment/maintenance complications: leakage, device migration, inability to secure precise alignment, durability under pulsatile flow.

Target Criteria for Sutureless Devices
According to this review, a “good” sutureless vascular anastomotic device should

1. Remove the need for vessel eversion.
2. Mitigate thrombosis, either by biodegradable materials or by embedding/releasing antithrombotic agents.
3. Be deployable easily and reliably in various anatomical situations.
4. Maintain patency over time; resist restenosis.
5. Be compatible with arterial wall properties (pressure, flow rates, elasticity).

Gaps / Challenges Identified

- Many devices are designed with veins or low-pressure vessels in mind; arteries are harder
- Few intraluminal devices have success in arteries.
- Tissue adhesives have potential but long-term data is sparse; durability, seal under high pressure, biocompatibility over time still open.
- Learning curve and device cost may limit adoption, especially in less resourced settings.

Project:

- Must allow arterial compatibility: able to withstand higher pressures; maintain flow; compatible elasticity.
- Must avoid excessive intimal injury. Device geometry, edges, method of apposition, any clamp or anchor mechanism should minimize trauma.
- For durability: materials must be selected for long term exposure to pulsatile arterial flow; possibly biodegradable or at least non-thrombogenic.
- A deployment mechanism that is easy, reliable, fast; minimization of ischemic time during anastomosis.
- Potential to include antithrombotic surfaces/coatings or drug elution to mitigate clot formation.
- Consider cost, manufacturability, and ease of use so device can be adopted widely (not just in high-resource centers).

Conclusions/action items: Existing sutureless approaches show promise especially in reducing time, ischemic exposure, and required skill, but their adaptation to arteries remains constrained by challenges in compliance matching, intimal damage, thrombosis, and durability—key issues your recoupler must address to be viable

Citation:

[1] J. G. Ribaudo *et al.*, “Sutureless vascular anastomotic approaches and their potential impacts,” *Bioactive Materials*, vol. 38, pp. 73–94, Apr. 2024, doi: https://doi.org/10.1016/j.bioactmat.2024.04.003.

https://pmc.ncbi.nlm.nih.gov/articles/PMC11061647/

2025/09/17 Hoberman/Scissor-Link Mechanisms

ALLISON RAUSCH - Sep 22, 2025, 11:58 AM CDT

Title: Hoberman/Scissor-Link Mechanisms

Date: 09/17/2025

Content by: Ally

Present: Ally

Goals: Extract a dilational, compliant ring architecture that preserves circularity while delivering a precise radial expansion, as a blueprint for an external arterial recoupler cuff.

Content:

Why: Same kinematics as the toy but flattened into a ring or short cuff. Gives controlled, near-circular expansion.
Lock ideas: over-center toggle at the final angle; micro ratchet pins at joint stops; bayonet twist collar over the joints.
Notes: Needs low-profile joints; can 3D-print micro-linkages in resin for form studies, then move to laser-cut metal

Problem
Design an annular compliant mechanism that can expand/contracts while preserving a circular shape (i.e., a dilational ring), avoiding link-and-joint assemblies.

Concept
The authors propose three compliant ring architectures that keep their cross-section nearly circular throughout motion—achieving ≈99% circularity over their usable range.

Range of motion
The best design expands its diameter by ~45% (large, smooth radial dilation).

Prototype & validation
A ring was 3D-printed in PETG (FFF). Experimental tests matched the model's predicted kinematics and stiffness, supporting the design method.

Why "shape-preserving" matters
When a ring dilates uniformly, it minimizes local curvature spikes and keeps the contact band smooth—useful anywhere circumferential pressure must be distributed evenly (e.g., around vessels). (Synthesis from the paper's objective/results.)

Design Takeaways:

Mechanism family to copy: a compliant dilational ring (no hinges) that scales uniformly—ideal for your outside-only requirement and tiny ~10% radial increase.
Tuning knobs: you can set the target expansion (to 3.3 mm) and radial force via flexure thickness, arc length, and pattern density; the paper shows the approach scales and matches experiments.
Manufacturability path: quick PETG/nylon prints for kinematics, then translate to PEEK, Ti-6Al-4V, or nitinol laser-cut/etched rings once geometry is frozen (the paper's PETG prototype demonstrates feasibility of rapid iteration).
Locking at final diameter: pair the compliant ring with a low-profile bayonet collar or collet sleeve that engages at 3.3 mm—locking concepts come from your mechanism exploration, while the ring supplies uniform dilation.

Conclusions/action items:

Citation: Compliant shape-preserving rings demonstrably keep near-perfect circularity and can be tuned for the small, controlled expansion your client specified, making this mechanism an excellent foundation for an outside-only, 3.0→3.3 mm locking recoupler design.

[1] K. W. A. Schreurs, G. Radaelli, and F. Alijani, "The design of a compliant shape-preserving ring," *Mechanism and Machine Theory*, vol. 151, p. 103918, Sep. 2020, doi: https://doi.org/10.1016/j.mechmachtheory.2020.103918.

https://www.sciencedirect.com/science/article/pii/S0094114X20301397

2025/09/17 Braided Stent Mechanics

ALLISON RAUSCH - Sep 22, 2025, 12:08 PM CDT

Title: Braided Stent Mechanics

Date: 09/17/25

Content by: Ally

Present:

Goals: Use the BCS study to extract braid + strip design rules (braid angle, NiTi count, strip thickness/width, and contact effects) that yield gentle, controllable radial expansion and maintained flexibility for an external, locking arterial cuff

Content:

A braided composite stent (BCS) woven from NiTi (nitinol) wires + PET strips was modeled and compared to a conventional braided nitinol stent (BNS) with the same braid pattern. Aim: quantify radial strength and longitudinal flexibility, and tease out how PET–NiTi interactions affect mechanics.

Geometry & materials (for the models)

- Both stents: OD 7 mm, length 15 mm, braid angle 65°.
- BNS: 32 helical NiTi wires (Ø 0.2 mm).
- BCS: 8 NiTi wires + 24 PET strips (PET thickness 0.12 mm, width derived from crossover spacing).
- NiTi modeled with a superelastic law; PET as elasto-plastic; contacts included with μ = 0.3. Abaqus/Explicit used.

Loading protocols (in silico)
- Radial compression test: mid-span compressed by a 5 mm rigid cylinder to 50% OD; reaction force used as radial strength metric (load–unload tracked).

- Pure bending test: ends counter-rotated to 60° total; bending moment recorded as flexibility metric.

Main findings
- Higher radial strength with PET strips, particularly at larger compressions—the PET “enforces constraints” on the braided network and shares load with NiTi.

- Flexibility (bending) was less sensitive to adding PET—i.e., the BCS retained favorable longitudinal flexibility relative to its strength gain.
- FEM results matched published experiments for a similar BCS configuration, supporting the model’s validity.

- The BCS could capture benefits of a covered stent (low porosity to limit tissue ingrowth/seal perforations) without the typical penalty of kinking/poor trackability seen in graft-covered devices—thanks to the compliant braid + strip architecture.

My Project:

- Braided-sleeve path: A braided cuff with a few self-expanding NiTi filaments interlaced with thin PET (or PEEK) strips can deliver uniform radial support while keeping longitudinal flexibility—use PET-like strips to tune radial force and reduce “porosity” of the cuff surface against adventitia. The paper shows how strip count/thickness meaningfully boosts radial strength.
- Friction & interaction matter: PET–NiTi contact and braid geometry control radial force vs. flexibility; you can exploit braid angle and strip thickness as levers to hit your ~10% expansion window without over-compressing the artery externally.
- Testing roadmap: Repurpose their radial compression and bending paradigms to characterize your cuff: (i) measure outward radial force across 3.0→3.3 mm, (ii) verify the cuff flexes with arterial motion without edge hotspots, (iii) use FEM to pre-screen braid patterns before benchtop tests.

Conclusions/action items: A braided composite architecture—NiTi filaments interlaced with thin PET-like strips—can substantially increase radial strength while preserving flexibility, providing a strong blueprint for an outside-only recoupler cuff that expands from 3.0 to 3.3 mm and stays stable after locking

Citation:

[1] Q. Zheng *et al.*, “Mechanical characterizations of braided composite stents made of helical polyethylene terephthalate strips and NiTi wires,” *Nanotechnology Reviews*, vol. 8, no. 1, pp. 168–174, Nov. 2019, doi: https://doi.org/10.1515/ntrev-2019-0016.

https://pmc.ncbi.nlm.nih.gov/articles/PMC9368628/

2025/09/21 CAR-27 Anastomosis Ring

ALLISON RAUSCH - Sep 22, 2025, 12:21 PM CDT

Title: CAR-27 Anastomosis Ring

Date: 09/21/2025

Content by: Ally

Present:

Goals: Use CAR-27's clinical experience to extract principles of uniform circumferential compression, deployment readiness cues, and leak verification

Content:

How it works
- A shape-memory NiTi (nitinol) compression ring with a polyethylene anvil; cooled to flatten the NiTi springs for deployment, then warmed to re-establish ring shape and apply circumferential compression until tissue bridges and the ring is expelled. Warm saline is used to hasten return to shape; completeness checked with an air-leak test. Typical expulsion is ~6–11 days per device description.

Study design
- Prospective, single-surgeon series of 79 elective left-sided colectomies with end-to-end CAR 27 anastomoses (Nov 2009–Jan 2011). Use was restricted to anastomoses at or above the intraperitoneal rectum (not low rectal/anal).

Operative course
- 70/79 performed laparoscopically (2 conversions, 2.9%). No surgical mortality. One intra-op disruption occurred when traction was applied while the ring was still cold; the anastomosis was redone with a new ring.

Short-term outcomes
- Leak: 1/79 (1.3%); managed with suture repair and diverting ileostomy. No clinical strictures reported. Patients generally did not notice expulsion timing.
- Short-term results suggest CAR 27 is a safe, efficacious alternative to hand-sewn or stapled anastomoses for indicated left-sided cases; authors call for larger studies and exploration of broader indications.

My project:

- Uniform circumferential compression works: The ring achieves patency with even radial compression and no permanent implants—supporting designs that create symmetric, shape-preserving apposition without intraluminal injury.
- Process control matters: The one intra-op failure occurred when tension was applied before thermal recovery—a reminder your device should include clear cues/feedback (visual/tactile) that it is ready/locked at target diameter (3.0→3.3 mm).
- Leak testing is standard: Pair any device deployment with an air-leak test or equivalent integrity check pathway.
- Anatomical limits: CAR 27's initial indication avoided low rectal sites; for arteries, translate this as: document site-specific limits (curvature, motion, diameter range) and ensure your cuff geometry maintains uniform wall shear and minimal trauma in those settings.

Conclusions/action items: A nitinol compression-ring paradigm achieved low early leak (approx 1.3%) with even radial force and no permanent implant, indicating that a shape-preserving, externally applied, lockable cuff with explicit readiness/lock feedback and post-deployment leak testing. Can plausibly match or improve anastomotic integrity for your arterial use case

Citation:

[1] J.-Y. Lee, "Early experience of the compression anastomosis ring (CARTM27) in left-sided colon resection," *World journal of gastroenterology*, vol. 17, no. 43, pp. 4787–4787, Jan. 2011, doi: https://doi.org/10.3748/wjg.v17.i43.4787.

https://pmc.ncbi.nlm.nih.gov/articles/PMC3229627/

202510/01 GEM Venous Coupler

ALLISON RAUSCH - Dec 09, 2025, 7:21 PM CST

Title: GEM Venous Coupler

Date: 10/1/2025

Content by: Ally

Present: N/A

Goals: Find existing coupler solutions

Content:

One widely adopted device in venous repair is the GEM Microvascular Anastomotic Coupler (Synovis/Baxter), which uses interlocking rings with metal pins to join everted vessel ends [6]. The coupler has demonstrated high patency rates exceeding 95% in venous systems and reduces operative time to an average of 7.5 minutes compared to traditional hand-sewing [7]. However, the GEM coupler and similar venous devices are unsuitable for arteries because arterial walls are thicker, less compliant, and exposed to higher intraluminal pressures, leading to misalignment and leakage under physiological conditions [2].

Conclusions/action items: Add to preliminary presentation

Citation:

[1] "Microvascular Anastomotic Coupler | Microvascular Anastomosis Couplers," *Synovismicro.com*, 2020. https://www.synovismicro.com/html/products/gem_microvascular_anastomotic_coupler.html (accessed Dec. 10, 2025).

[6] "Synovis Surgical, a division of Baxter, licenses Arterial Everter transplant surgery technology from U-M," UM - Innovation Partnerships. Accessed: Oct. 08, 2025. [Online]. Available: https://innovationpartnerships.umich.edu/stories/synovis-surgical-a-division-of-baxter-licenses-arterial-everter-transplant-surgery-technology-from-u-m/

[7] C. Ohayon *et al.*, "Efficiency and outcomes in microvascular anastomosis: A meta-analysis of mechanical versus manual techniques," *J. Cranio-Maxillofac. Surg.*, vol. 53, no. 10, pp. 1720–1730, Oct. 2025, doi: 10.1016/j.jcms.2025.07.015.

[2] "Arteries vs. Veins: What's the Difference?" Accessed: Oct. 08, 2025. [Online]. Available: https://www.webmd.com/heart/difference-between-arteries-and-veins

2025/10/04 Magnetic Compression Anastomosis

ALLISON RAUSCH - Dec 09, 2025, 7:26 PM CST

Title: Magnetic Compression Anastomosis

Date: 10/4/2025

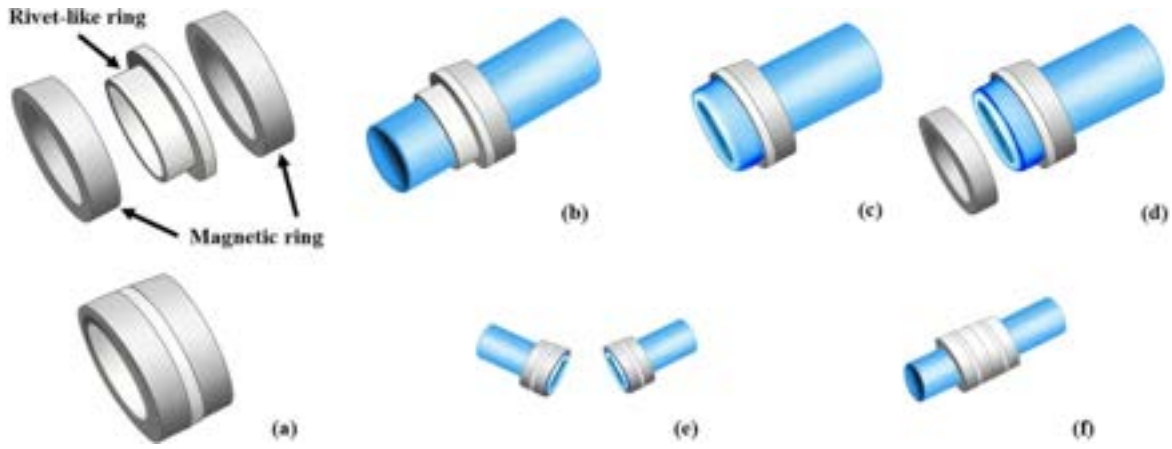
Content by: Ally

Present: Ally

Goals: Find alternative anastomosis methods and their pitfalls

Content:

Alternative designs explored in literature include magnetic compression anastomosis (MCA) systems and external cuff methods. MCA devices use rare-earth magnets to approximate and fuse vessel ends without sutures [9]. Although they have shown promise in gastrointestinal applications, studies report risks of stenosis, poor alignment, and pressure-induced damage when adapted for vascular use [9], [10]. Similarly, external cuff techniques, which evert the vessel over a support tube, reduce operative time but often compromise vascular compliance and have been associated with thrombosis and intimal hyperplasia [4], [11].



Conclusions/action items: Add to preliminary report

Citations:

[4] J. G. Ribaudo *et al.*, "Sutureless vascular anastomotic approaches and their potential impacts," *Bioact. Mater.*, vol. 38, pp. 73–94, Apr. 2024, doi: 10.1016/j.bioactmat.2024.04.003

[9] M.-M. Zhang *et al.*, "Magnetic compression anastomosis for reconstruction of digestive tract after total gastrectomy in beagle model," *World J. Gastrointest. Surg.*, vol. 15, no. 7, pp. 1294–1303, July 2023, doi: 10.4240/wjgs.v15.i7.1294.

[10] T. Kamada *et al.*, "New Technique for Magnetic Compression Anastomosis Without Incision for Gastrointestinal Obstruction," *J. Am. Coll. Surg.*, vol. 232, no. 2, pp. 170-177.e2, Feb. 2021, doi: 10.1016/j.jamcollsurg.2020.10.012.

[11] D. J. Coleman and M. J. Timmons, "Non-suture external cuff techniques for microvascular anastomosis," *Br. J. Plast. Surg.*, vol. 42, no. 5, pp. 550–555, Sept. 1989, doi: 10.1016/0007-1226(89)90043-X.

2025/10/07 Intraluminal Stents

ALLISON RAUSCH - Dec 09, 2025, 7:30 PM CST

Title: Intraluminal Stents

Date: 10/7/2025

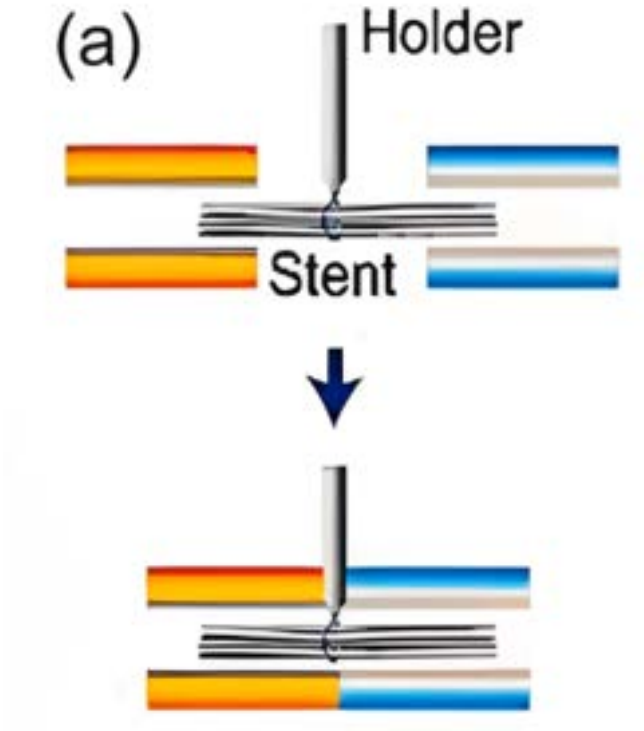
Content by:

Present: Ally

Goals: Ally

Content:

Recent work has investigated placing supportive structures, intraluminal stents, inside the lumen to maintain patency during healing while resorbing over time. These devices can shorten procedure times and do not require eversion but risk disrupting endothelial flow dynamics, provoking thrombosis, and complicating long-term healing [13]. Dissolvable scaffolds, which work to maintain mechanical support during early healing then degrade, seem to be a compelling path as well. Although these scaffolds prevent acute inflammation and thrombosis, challenges remain in tailoring degradation rates, mechanical stability, and biocompatibility concurrently [4].



Conclusions/action items: Compare to other solutions

Citations:

[13] P. Senthil-Kumar *et al.*, “An intraluminal stent facilitates light-activated vascular anastomosis,” *J. Trauma Acute Care Surg.*, vol. 83, no. 1 Suppl 1, pp. S43–S49, July 2017, doi: 10.1097/TA.0000000000001487.

[4] J. G. Ribaudo *et al.*, “Sutureless vascular anastomotic approaches and their potential impacts,” *Bioact. Mater.*, vol. 38, pp. 73–94, Apr. 2024, doi: 10.1016/j.bioactmat.2024.04.003.

2025/11/10 Pediatric Stent

ALLISON RAUSCH - Dec 09, 2025, 7:49 PM CST

Title: Pediatric Stent

Date: 11/10/25

Content by: Ally

Present: NA

Goals: Find out how pediatric stents are made (very small scale)

Content:

Minima Stent:

- The Minima stent is the first cardiac stent specifically designed for newborns, infants, and young children.
- It was approved by the FDA in August 2024.
- It is used to treat:
    - Aortic coarctation
    - Branch pulmonary artery stenosis
- The stent is designed to expand as a child grows, from about 5 mm up to 24 mm, allowing it to potentially last into adulthood.

Why This Is Important

- Before the Minima stent, most stents used in children were designed for adults, not babies.
- Previous treatment options included:
    - Balloon angioplasty (often not long-lasting)
    - Repeat open-heart surgeries as the child grew
- The Minima stent provides a minimally invasive alternative using catheter-based implantation.
- Most babies can go home the next day after the procedure.

How the Stent Works

- The stent is crimped onto a balloon and delivered through a thin catheter into very small blood vessels.
- It can be compressed to less than 2 mm in diameter for delivery.
- Once in position, the balloon is inflated to expand the stent and open the narrowed vessel.
- As the child grows, the stent can be re-expanded using a balloon during future catheter procedures.
- The stent is typically expanded two to four times over the patient’s lifetime.

Clinical Trial Results

- FDA approval was based on a multi-center clinical study with 42 pediatric patients.
- 97.6% of patients had successful relief of vessel narrowing.
- At six months:
    - No patients required additional surgery
    - No major device-related adverse events were reported

Significance

- Provides a long-term, growth-accommodating solution for infants with congenital heart vessel narrowing.
- Reduces the need for multiple open-heart surgeries.
- Represents a major advancement in pediatric interventional cardiology by offering a purpose-built device for very small patients rather than adapting adult stents.

Conclusions/action items: See if these findings can be applied to our manufacturing

Citation:

[1] "FDA Approves First-of-Its-Kind Cardiac Stent for Babies," *Children's Hospital Los Angeles*, 2024. https://www.chla.org/blog/experts/fda-approves-first-its-kind-cardiac-stent-babies (accessed Dec. 10, 2025).

2025/09/20 Preliminary Design Mechanisms

ALLISON RAUSCH - Sep 22, 2025, 12:10 PM CDT

Title: Preliminary Design Mechanisms

Date: 09/20/25

Content by: Ally

Present:

Goals: Amalgamate design mechanism ideas into one spot.

Content:

Lowest profile, few parts: Helical-cut compliant ring or nitinol pre-set ring.
Most deterministic lock positions: Collet & taper or ratcheting micro-band.
Easiest breadboard prototype: Ratcheting band (resin print), braided sleeve + collet, or helical-cut PET/PEEK tube.
Best for gentle, uniform pressure: Braided sleeve or shape-memory ring.

Locking Concepts to pair with above:

- **Pawl-and-ratchet** with ~0.05–0.10 mm step size
- **Bayonet quarter-turn** with hard stops at 3.3 mm
- **Over-center snap** (toggle) tuned to trip at 3.3 mm
- **Collet + detented taper** (can add audible/tactile click)
- **Thermal set** (nitinol: final diameter is the “lock”)

Conclusions/action items: Create holistic design concepts for Preliminary Design Matrix

2025/10/29 Spike Stent Design

ALLISON RAUSCH - Dec 09, 2025, 5:00 PM CST

Title: Spike Stent Design

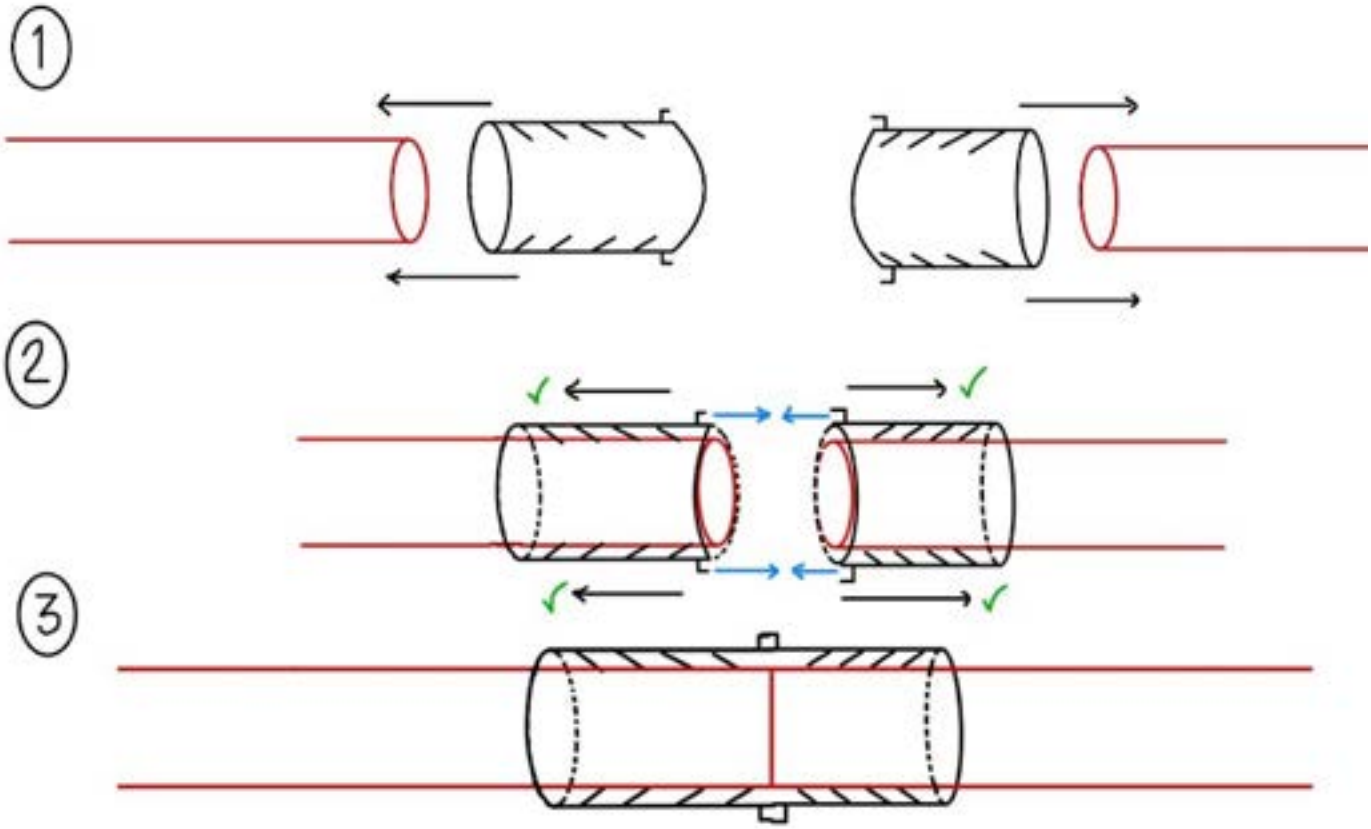
Date: 10/29/2025

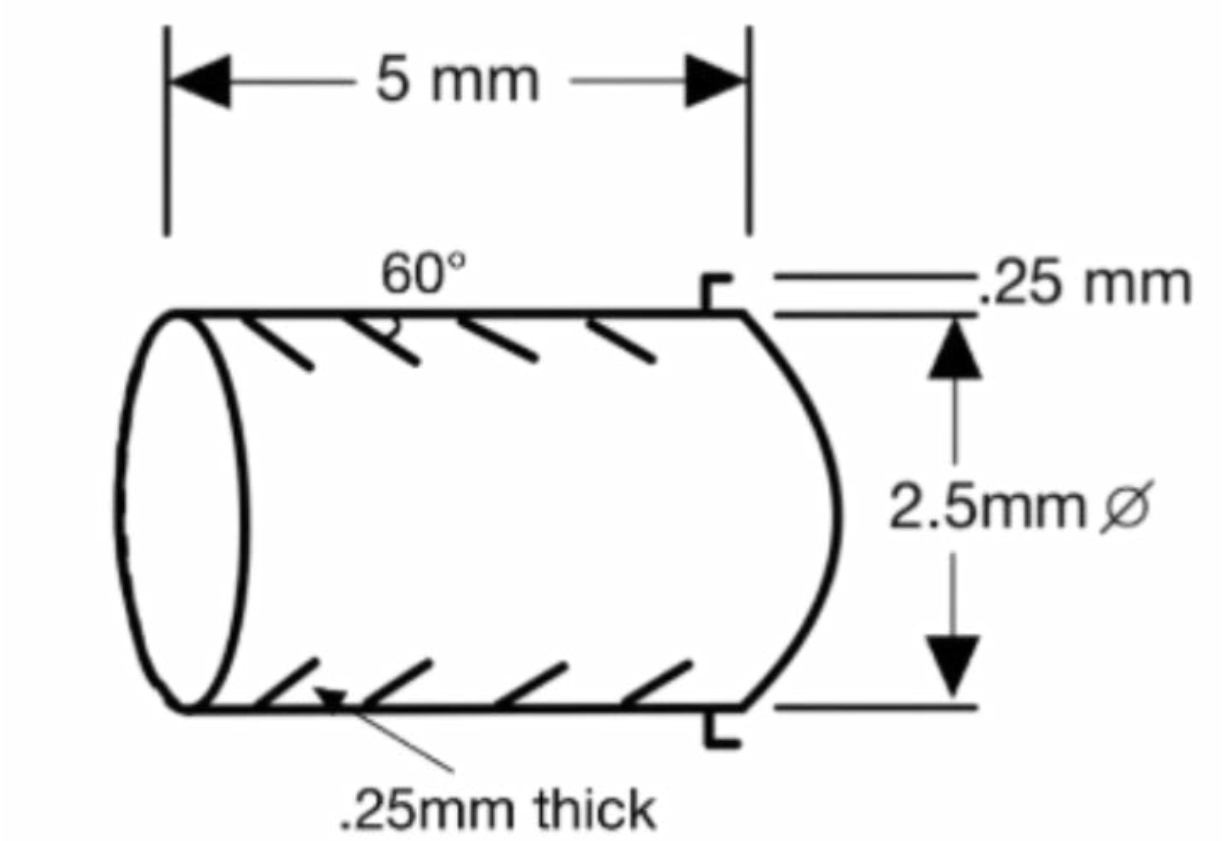
Content by: all

Present: all

Goals: Create a stent design

Content:





The second design, the Spike Stent, features two directionally spiked external stents, similar to a cuff, surrounding the adventitia of each end of the artery. Machined from a strong, corrosion-resistant, and biocompatible metal, these cuffs and the associated spikes securely anchor the exterior stent in place, minimizing migration while maintaining vessel integrity and biocompatibility. These cuffs, machined to the desired artery size, have small, short spikes, designed for digging into just the adventitial layer surrounding the vessel, avoiding damage to the lumen while preventing the artery from sliding out of the cuff. These cuffs are slid over the arteries until aligned with each end of the cut, as depicted in Figure 8 above. As the directional spikes prevent the cuffs from sliding off of the artery, and the two ends can be joined together via small clips on the exterior of the cuff. This cuffing mechanism allows for a very quick, sutureless process in anastomosis procedures.

Conclusions/action items: Add to preliminary report

2025/11/01 Sock Clamp Design

ALLISON RAUSCH - Dec 09, 2025, 4:59 PM CST

Title: Sock Clamp Design

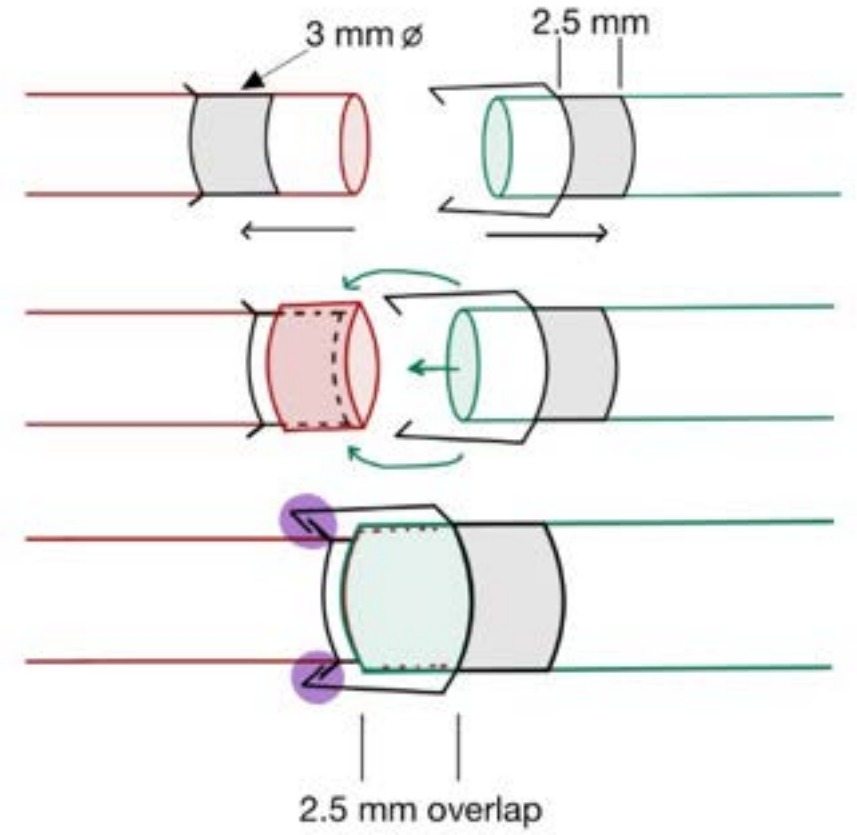
Date: 11/1/2025

Content by: All

Present: All

Goals: Create a design for a possible coupler model

Content:



The first proposed design, the Sock Clamp, shown above, features two tubular clamps with clips for locking the arteries together that function similar to a side-release buckle. A suitably strong and biocompatible material, such as Stainless Steel 316L, would be used to ensure no complications with durability or potential thrombosis would occur. One clip uses two small prongs facing away from the cut on the proximal artery (red), while the other clip uses two extending arms reaching out over the end of the distal (green) artery. These clamps would be secured around the perimeter of the arteries using a pressure-based mechanism. The microsurgeon would utilize this device by first fitting the tubular clamps around each artery, then everting the proximal artery back over the clamp. The distal end would then sleeve over the proximal artery, and the two-point clips would lock together, securing the arteries together. This device eliminates the need for sutures, the most time consuming factor in an anastomosis. The quick arterial connection also allows for excellent intima overlap, facilitating faster regrowth and healing.

Conclusions/action items: Add this to the preliminary report

2025/11/05 Nitinol Expanding Stent

ALLISON RAUSCH - Dec 09, 2025, 5:04 PM CST

Title: Nitinol Expanding Stent Design

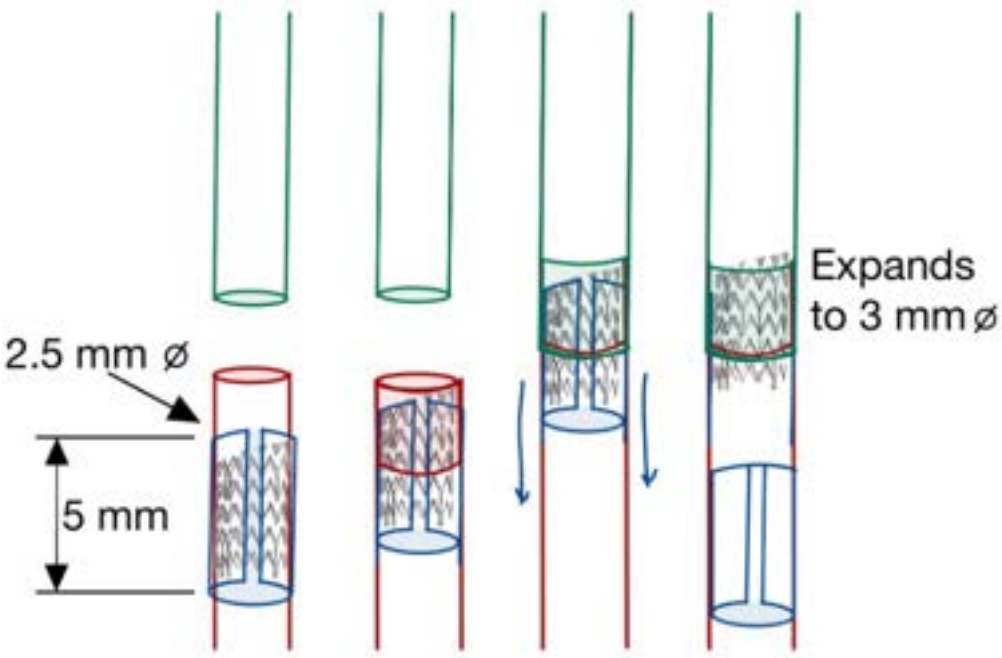
Date: 11/5/2025

Content by: all

Present: all

Goals: Create another stent design

Content:



The Expandable Stent design is a two-step design utilizing an expanding nitinol stent housed within a loader tube. This design, pictured above, uses nitinol, a nickel-titanium alloy known fo its superelasticity and shape memory, and a material widely used in vascular procedures [23]. The shape memory aspect allows for the stent to be deformed at a cooler temperature, such as t operating room, before returning to its original manufactured shape at near-homeostatic temperatures. The loading tube will be machined from a strong yet flexible material, with a low coefficient of friction being a key requirement. PTFE is a viable choice for this material, as its inherently low friction coefficient gives it anti-friction properties. Strength or flexibility limitations of PTFE can also be overcome by adding suitable fillers selected to increase mechanical performance [24]. The stent, machined to 3mm, will be inserted into the loading tube an fit around the proximal artery. The sequence of contact from interior to exterior is artery, stent, then loading tube. At this point, the microsurgeon will then use the loading tube to compress t diameter of the nitinol stent to be smaller than the artery, making for an easier eversion over the device. Once the artery is everted, the distal artery (depicted in Figure as green) is then sleev over the proximal end. At this point, the loading tube can then be slid away from the junction and off of the proximal artery, leaving the stent to expand back to its 3mm diameter, expanding the arterial lumen, and creating a seal between the arteries. If needed, a suture can then be tied in a clamp-like manner around the junction, reinforcing the seal.

Conclusions/action items: Add to preliminary report

Citations:

[23] "Fracture Fixation Using Shape-Memory (Ninitol) Staples - ClinicalKey." Accessed: Oct. 08, 2025. [Online]. Available: https://www.clinicalkey.com/?adobe_mc=MCMID%3D21082904837742235984535863003632819506%7CMCORGID%3D4D6368F454EC41940A4C98A6%2540AdobeOrg%7CTS%3D1759858884#!/content/journal s2.0-S0030589819300033

[24] "Mechanical and Tribological Properties of Polytetrafluoroethylene Composites with Carbon Fiber and Layered Silicate Fillers." Accessed: Oct. 08, 2025. [Online]. Available: https://www.mdpi.com/1420-3049/24/2/224

2025/11/17 Design Consult

ALLISON RAUSCH - Dec 09, 2025, 4:27 PM CST

Title: Design Consult Nitinol Stent Apparatus

Date: 11/17/2025

Content by: Ally

Present: All

Goals: Use patented design for nitinol heat treatment

Content:

PDF below

Conclusions/action items: Take to Team Labs

ALLISON RAUSCH - Dec 09, 2025, 4:28 PM CST

Download

Nitinol_Stent_Apparatus.pdf (1.98 MB)

2025/11/18 Final Design

ALLISON RAUSCH - Dec 09, 2025, 6:00 PM CST

Title: Final Design

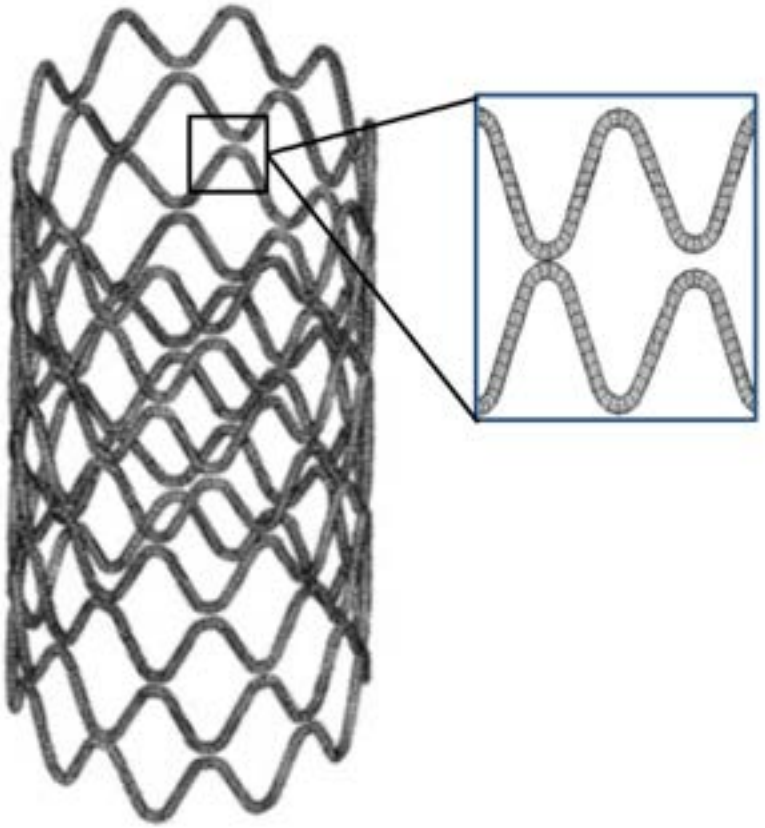
Date: 11/18/2025

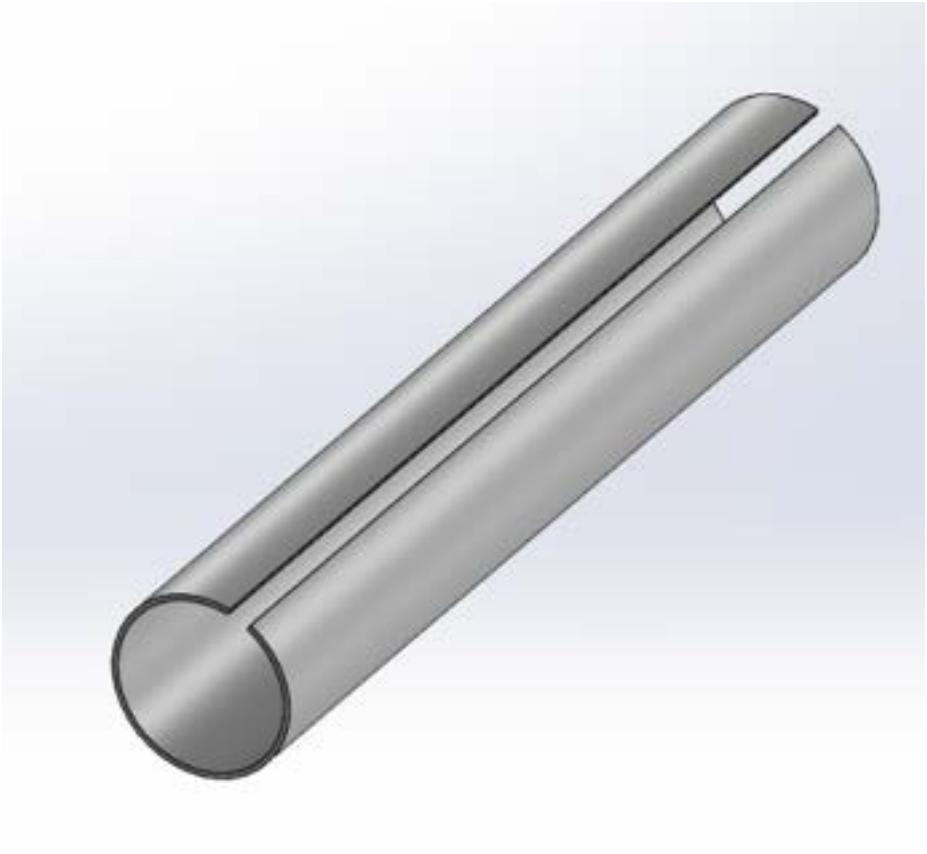
Content by: all

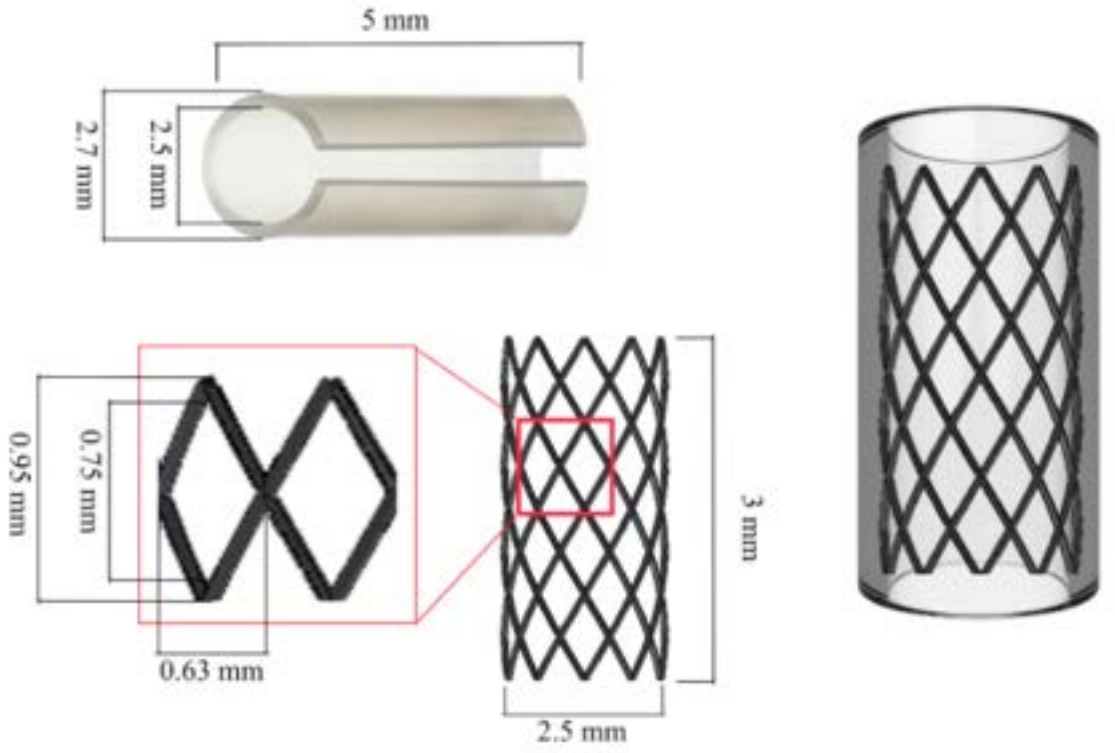
Present: all

Goals: Display final prototype design

Content:







The proposed final design is a nitinol stent that will be inserted into a PTFE loader tube during implantation. During implantation the device will be restricted to the maximum allowable diameter set by the loader tube. Once proper eversion and overlaying of the arterial ends is complete, the loader tube can be removed and the nitinol stent will have the ability to expand to the machined diameter, set to match the artery. Elastic properties are still maintained in the fully expanded state allowing the device to respond dynamically to deviations in arterial pressures.

Conclusions/action items: Work on fabrication protocol

2025/10/28 Training documentation - green and red permit

ALLISON RAUSCH - Oct 28, 2025, 12:46 PM CDT

Title: Training Documentation - green and red permit

Date: 10/28/25

Content by: Ally

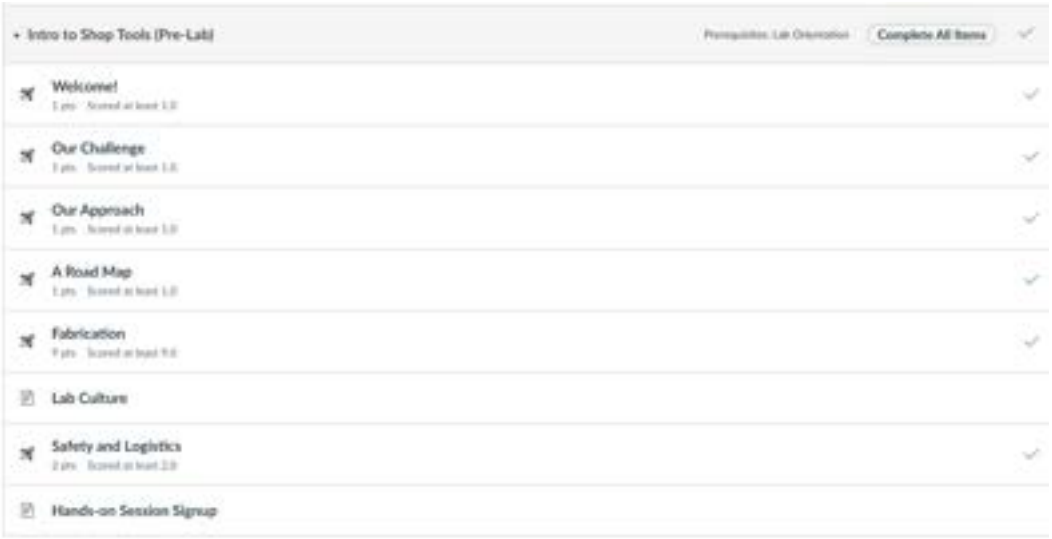
Present: Ally

Goals: Complete green and red permit in order to use all machines needed for BME 201 Design.

Content:

I completed these trainings prior to this semester

Intro to machining - mill completed February 9th, Lathe completed February 5th



Conclusions/action items: Practice on machines in order to fabricate properly

2025/10/28 Biosafety and OSHA training

ALLISON RAUSCH - Oct 28, 2025, 12:47 PM CDT

Title: Biosafety and OSHA training

Date: 10/28/25

Content by: ally

Present: ally

Goals: complete training in order to start BME 201 course

Content:

attached in pdf

Conclusions/action items: None

ALLISON RAUSCH - Apr 30, 2024, 10:50 AM CDT

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2025/10/28 RARC Training Documentation

ALLISON RAUSCH - Oct 28, 2025, 12:49 PM CDT

Title: RARC Training documentation

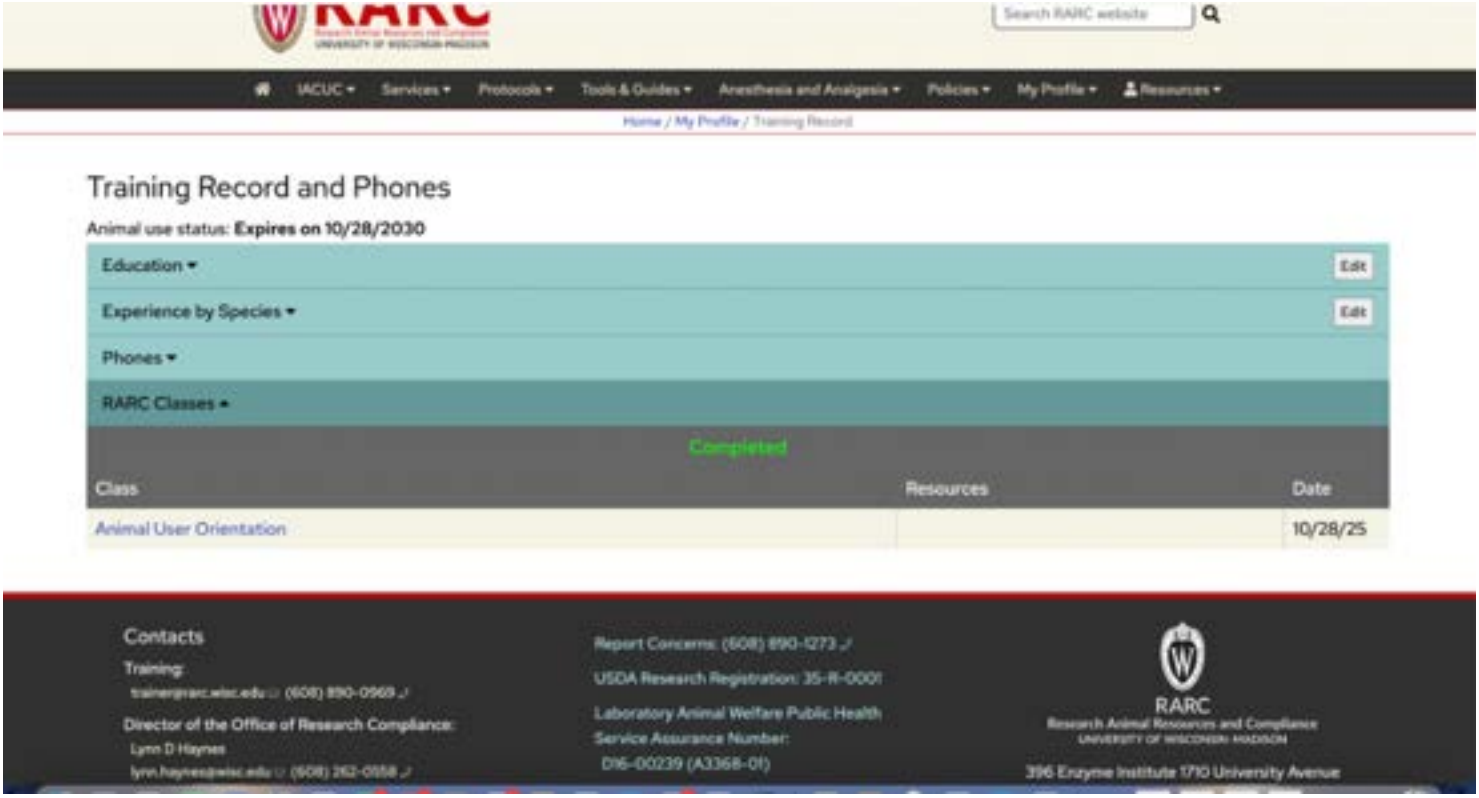
Date: 10/28/25

Content by: Ally

Present: N/A

Goals: Complete RARC training

Content:



Conclusions/action items: Submit on canvas for continued training proof.

2025/09/23 - Use of Microvascular Anastomotic Couplers in Traumatic Wrist Injuries - Product Design Specification

ARSHIYA CHUGH - Sep 23, 2025, 8:26 PM CDT

Title: Use of Microvascular Anastomotic Couplers in Traumatic Wrist Injuries - Product Design Specification

Date: 9/23/2025

Content by: Arshiya (Ria) Chugh

Present: N/A

Goals: Assess whether couplers improve safety and efficiency in traumatic wrist revascularization compared to sutures.

Content:

Key Concepts:

- Traumatic wrist injuries often require urgent revascularization.
- Couplers are ring-based devices that mechanically connect vessel ends without sutures.
- Aim: reduce time and technical burden while maintaining safety.

Methods & Approach:

- Clinical series of traumatic wrist patients treated with couplers.
- Outcomes: patency, complications, operative time.

Key Findings:

- High patency rates observed postoperatively.
- Reduced operative time compared to expected suturing.
- Minimal complications, device performed reliably.

Clinical/Pathological Implications:

- Couplers allow rapid restoration of blood flow, reducing ischemia risk.
- May expand access to microsurgical repair in trauma settings where speed is critical.

Relevance to Arterial Coupler Redesign:

- Confirms clinical utility of device-based anastomosis in high-stakes trauma.
- Design should prioritize quick deployment and reproducible patency.
- Suggests opportunity for trauma-focused adaptations (easy-to-use, robust under emergency conditions).

[1] T. T. Mai, L. T. T. Nguyen, and P. D. Nguyen, “Efficiency and safety of microvascular anastomotic coupler for wrist revascularization in traumatic injuries,” JPRAS Open, vol. 41, pp. 252–259, Sept. 2024, doi: 10.1016/j.jpra.2024.06.017.

Conclusions/action items: Couplers can effectively reduce operative burden in trauma scenarios. Our design must emphasize rapid usability under stress conditions while ensuring patency. There could be potential in integrating emergency use cases into design requirements.

2025/09/11 - Safe, Fast, and Minimally-Assisted Microsurgical Anastomosis with Combined Open-Loop Suturing and Airborne Tying

ARSHIYA CHUGH - Sep 11, 2025, 4:43 PM CDT

Title: Safe, Fast, and Minimally-Assisted Microsurgical Anastomosis with Combined Open-Loop Suturing and Airborne Tying

Date: 9/11/2025

Content by: Arshiya (Ria) Chugh

Present: N/A

Goals: Understand how the open-loop suture + airborne tying technique improves microsurgical anastomosis.

Content:

Background

- Standard technique: simple interrupted sutures with conventional knot tying.
- Issues: risk of back-wall catch, time-consuming, requires assistant.
- Open-loop suturing: keeps lumen visible, reduces technical failure, faster.
- Airborne tying: speeds up knotting, prevents suture sticking.

Methods

- Experimental**:** 40 rat femoral artery anastomoses (0.6 mm).
    - Group I: interrupted sutures + conventional tying.
    - Group II: open-loop sutures + airborne tying.
    - Measured: anastomosis time + patency.
- Clinical: Retrospective review of 104 human anastomoses (free flap transfers + replantations).

Results

- Experimental**:**
    - Control: 779.65 s (~13 min).
    - Open-loop + airborne: 527.4 s (~8.7 min).
    - Statistically significant ($p<0.001$).
    - Patency: no significant difference.
- Clinical**:**
    - Free flap transfers (n=17, 15 pts): 94.2% success.
    - Replantations (n=18, 16 pts): 95.1% success.
    - Total anastomoses: 104.
    - Average time ~9 minutes per anastomosis.

Technical Notes

- Small vs. large loops based on vessel size.
- Loops made far-to-near to avoid entanglement.

- Keep moist (not wet) environment for easy loop handling.
- Airborne tying easier with larger sutures and lower magnification.
- Clean, precise instruments essential.

[1] G. Sert, “Safe, fast, and minimally-assisted microsurgical anastomosis with combined open-loop suturing and airborne tying: a clinical and experimental study,” *Turkish Journal of Trauma and Emergency Surgery*, 2023, doi: https://doi.org/10.14744/tjtes.2023.79702.

Conclusions/action items: Open-loop + airborne tying significantly reduces anastomosis time without sacrificing patency. Clinically safe with high success rates for both free flaps and replantations. Could be valuable in reducing ischemia time during complex reconstructions.

2025/09/23 - Alternative Suture Sizes for Early Microsurgery Training - Product Design Specification

ARSHIYA CHUGH - Sep 23, 2025, 8:38 PM CDT

Title: Hemodynamic Significance of Coronary Narrowing Length

Date: 9/23/2025

Content by: Arshiya (Ria) Chugh

Present: N/A

Goals: Investigate whether larger sutures can ease the steep learning curve in early microsurgery training.

Content:

Background:

- Microsurgery requires mastering delicate handling of fine sutures.
- Steep learning curve leads to high error rates early in training.
- Hypothesis: using larger sutures initially may aid skill acquisition.

Methods:

- In vivo rat models used for practice anastomoses.
- Compared outcomes across different suture sizes for beginners.

Key Findings:

- Larger suture sizes improved early learning outcomes.
- Allowed trainees to focus on technique without being overwhelmed.
- No major compromise to basic skill transfer.

Clinical/Pathological Implications:

- Training approaches can reduce error and improve surgeon confidence.
- Could accelerate readiness for clinical practice.

Relevance to Arterial Coupler Redesign:

- Suggests value of designing devices with intuitive use, easing learning curve.
- Devices should not require mastery of ultra-fine handling for safe use.
- Training modules for device adoption may benefit from scaled learning.

[1] Y. Zheng, J. J. Corvi, J. R. Paladino, and Y. Akelina, “Smoothing the steep microsurgery learning curve: considering alternative suture sizes for early-stage microsurgery training with in vivo rat models,” Eur. J. Plast. Surg., vol. 44, no. 6, pp. 733–737, Dec. 2021, doi: 10.1007/s00238-021-01850-0.

Conclusions/action items: Simplifying training accelerates surgeon adoption. Our coupler should minimize the microsurgical learning barrier. Evaluate user-training protocols alongside prototype testing.

2025/09/23 - Enhancing Visibility in Supermicrosurgical Anastomosis - Product Design Specification

ARSHIYA CHUGH - Sep 23, 2025, 8:43 PM CDT

Title: Enhancing Visibility in Supermicrosurgical Anastomosis

Date: 9/23/2025

Content by: Arshiya (Ria) Chugh

Present: N/A

Goals: Compare lumen-enhancing visibility techniques for supermicrosurgical vascular anastomosis.

Content:

Key Concepts:

- Supermicrosurgery involves extremely small vessels (<0.8 mm).
- Precision depends heavily on lumen visualization.
- Various adjunct techniques exist to enhance visibility.

Methods & Approach:

- Comparative study of different lumen-enhancing methods during anastomosis.
- Metrics: accuracy, error rates, and procedure times.

Key Findings:

- Certain visualization methods significantly improved outcomes.
- Enhanced lumen clarity reduced misplacement and improved success rates.

Clinical/Pathological Implications:

- Better visualization improves patient safety and reduces failure.
- Could expand indications for supermicrosurgical procedures.

Relevance to Arterial Coupler Redesign:

- Our coupler should consider how to assist or not hinder visibility during placement.
- Potential integration of features (contrast, transparency, lumen guides).
- Visibility improvements are critical at very small vessel scales.

[1] V.-A. Ratoiu et al., “Supermicrosurgical Vascular Anastomosis—A Comparative Study of Lumen-Enhancing Visibility Techniques,” J. Clin. Med., vol. 14, no. 2, p. 555, Jan. 2025, doi: 10.3390/jcm14020555.

Conclusions/action items: Visibility is a major determinant of success in supermicrosurgery. Our device must be designed to optimize or preserve clear lumen visualization. Integrate visualization considerations into CAD design of coupler.

2025/09/23 - Proteins, Platelets, and Blood Coagulation at Biomaterial Interfaces - Product Design Specification

ARSHIYA CHUGH - Sep 23, 2025, 9:03 PM CDT

Title: Proteins, Platelets, and Blood Coagulation at Biomaterial Interfaces

Date: 9/23/2025

Content by: Arshiya (Ria) Chugh

Present: N/A

Goals: Examine how blood interacts with biomaterial surfaces, focusing on protein adsorption, platelet adhesion, and coagulation - critical for thrombosis risk in vascular devices.

Content:

Key Concepts:

- When blood contacts a biomaterial, protein adsorption is the first event, dictating downstream cell interactions.
- Adsorbed proteins (fibrinogen, albumin, von Willebrand factor) influence platelet adhesion and activation.
- Platelet adhesion triggers clotting cascades, thrombin generation, and fibrin formation.

Biological Mechanisms:

- Protein Layer Formation: Rapid adsorption alters conformation; denatured fibrinogen can increase platelet adhesion.
- Platelet Activation: Integrins (e.g., GPIIb/IIIa) bind proteins, releasing ADP and thromboxane A2, amplifying aggregation.
- Coagulation Cascade: Tissue factor pathway activates thrombin, stabilizing clot with fibrin.

Material Properties Influencing Thrombosis:

- Surface chemistry (hydrophobicity, charge) alters protein adsorption profile.
- Surface topography influences platelet adhesion and activation.
- Biocompatible coatings (heparin, PEG) reduce clotting risk.

Clinical/Pathological Implications:

- Uncontrolled thrombosis leads to device occlusion.
- Material selection and surface modification directly impact device safety.

Relevance to Arterial Coupler Redesign:

- Coupler materials must resist thrombosis by minimizing platelet adhesion and controlling protein adsorption.
- Surface engineering (coatings, texturing) should be incorporated to improve hemocompatibility.
- Testing must include blood-contact studies for coagulation and platelet activation.

[1] L.-C. Xu, J. W. Bauer, and C. A. Siedlecki, “Proteins, platelets, and blood coagulation at biomaterial interfaces,” Colloids Surf. B Biointerfaces, vol. 124, pp. 49–68, Dec. 2014, doi: 10.1016/j.colsurfb.2014.09.040.

Conclusions/action items: Protein adsorption and platelet activation are central to biomaterial thrombogenicity. Our coupler design must integrate surface modifications that reduce unwanted coagulation. Review available antithrombogenic coatings and consider testing in flow loop models.

2025/09/23 - Titanium Vascular Anastomotic Device in Pig Jugular Veins - Product Design Specification

ARSHIYA CHUGH - Sep 23, 2025, 8:33 PM CDT

Title: Titanium Vascular Anastomotic Device in Pig Jugular Veins

Date: 9/23/2025

Content by: Arshiya (Ria) Chugh

Present: N/A

Goals: Determine the biocompatibility and patency of a novel titanium vascular device in a preclinical model.

Content:

Key Concepts:

- Material choice is critical for implantable vascular devices.
- Titanium offers corrosion resistance, biocompatibility, and strength.
- Tested in pig jugular veins to mimic clinical conditions.

Methods & Approach:

- Implanted titanium anastomotic devices in pigs.
- Monitored for tissue integration, inflammatory response, and vessel patency.

Key Findings:

- Devices maintained patency over study duration.
- Low inflammatory and fibrotic responses noted.
- Showed strong compatibility with vascular tissue.

Clinical/Pathological Implications:

- Confirms titanium’s value for vascular device fabrication.
- Long-term safety and integration are feasible.

Relevance to Arterial Coupler Redesign:

- Supports titanium as a viable material for coupler design.
- Biocompatibility is critical for preventing thrombosis and restenosis.
- Reinforces need for material testing in both large and small animal models.

[1] S. An et al., “Biocompatibility and patency of a novel titanium vascular anastomotic device in a pig jugular vein,” Sci. Rep., vol. 11, no. 1, p. 17512, Sept. 2021, doi: 10.1038/s41598-021-97157-y.

Conclusions/action items: Titanium demonstrates excellent performance as a vascular device material. Our design should consider titanium or alloys with similar properties. A next step could be to evaluate surface treatments (coatings, texturing) to further reduce thrombogenicity.

2025/09/11 - Mechanotransduction in Blood Vessels: Shear Stress and Circumferential Stretch

ARSHIYA CHUGH - Sep 11, 2025, 4:36 PM CDT

Title: Mechanotransduction in Blood Vessels: Shear Stress and Circumferential Stretch

Date: 9/11/2025

Content by: Arshiya (Ria) Chugh

Present: N/A

Goals: Understand how shear stress and circumferential stretch regulate vascular biology. Connect physiological and pathological responses to device design considerations.

Content:

Key Concepts:

- Blood vessels experience mechanical forces from blood pressure (circumferential stretch) and blood flow (shear stress).
- These forces regulate endothelial and smooth muscle cell (SMC) function, impacting vessel morphology, tone, and biochemical signaling.
- Proper physiological stresses maintain vascular homeostasis (e.g., nitric oxide (NO) production, oxidative balance); abnormal stresses can cause dysfunction (e.g., altered stiffness, vasorelaxation).

Blood Vessel Structure & Mechanics:

- Arteries consist of intima (endothelium), media (smooth muscle), adventitia.
- Shear stress: friction from blood flow on endothelium → vasodilation, NO release.
- Circumferential stretch: vessel distension from blood pressure → SMC contraction, Ang II release, NADPH oxidase activation.
- Material properties of vessel wall affect stress-strain response; remodeling occurs in disease (hypertension, diabetes).

Key Biochemical Pathways:

- Shear stress: activates PECAM-1, integrins, VEGFR2, leading to eNOS phosphorylation → NO release; also triggers prostacyclin (PGI2) → vasodilation & anti-thrombosis.
- Circumferential stretch: activates AT1R (ligand-dependent/independent) → NADPH oxidase → superoxide → endothelial dysfunction; integrins trigger Rho/FAK pathway → actin polymerization.
- Overlap: integrins, NADPH oxidase, NO, PGI2 common to both; responses differ (shear generally protective, stretch can promote oxidative stress if excessive).

Clinical & Pathological Implications:

- Low or reversing shear stress → increased oxidative stress → higher risk of atherosclerosis.
- Hypertension → chronic circumferential stretch → vessel remodeling, increased wall thickness.
- Understanding these pathways helps inform pharmacological interventions and potential design improvements for vascular devices.

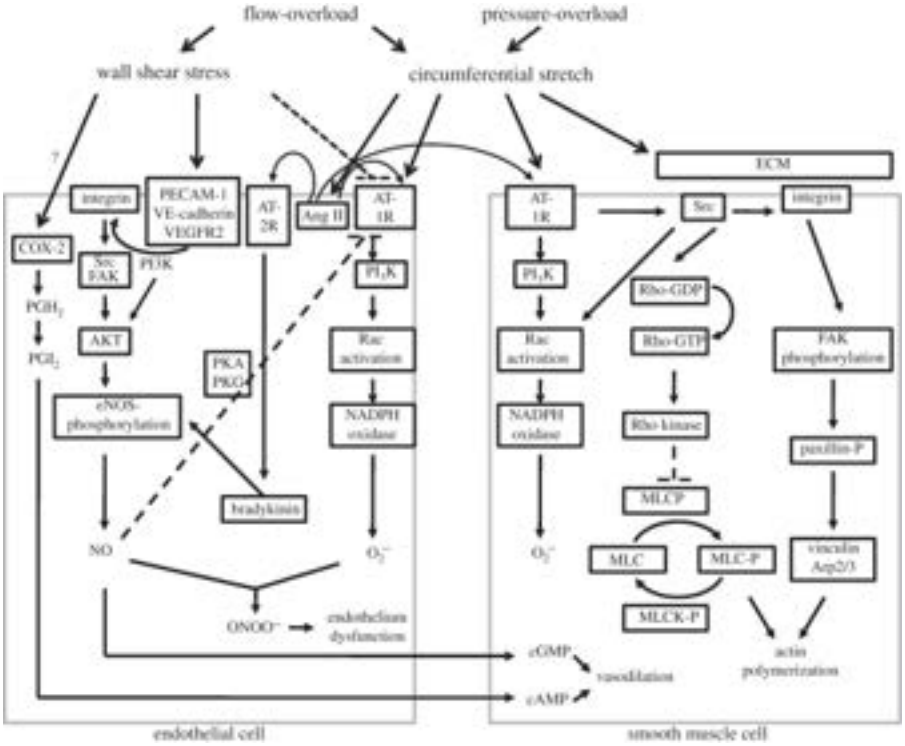


Figure 1

This diagram shows how flow and pressure affect endothelial and smooth muscle cells. Solid arrows show activation, and dashed lines show inhibition.

Relevance to Arterial Coupler Redesign:

- Adjustable stent/cuff should account for mechanical forces on vessel walls to prevent endothelial damage.
- NO and oxidative stress pathways are crucial: device should avoid triggering excessive superoxide or reducing NO bioavailability.
- Integrin and ECM interactions inform how coupler attachment affects SMC and endothelial behavior.
- Consider circumferential compliance and shear stress distribution to minimize remodeling or thrombosis.

[1] D. Lu and G. S. Kassab, “Role of shear stress and stretch in vascular mechanobiology,” Journal of The Royal Society Interface, vol. 8, no. 63, pp. 1379–1385, Jul. 2011, doi: https://doi.org/10.1098/rsif.2011.0177.

Conclusions/action items: Mechanical forces like shear stress and circumferential stretch play key roles in endothelial and smooth muscle cell function by regulating NO, prostaglandins, and oxidative stress. Understanding these pathways can inform the design of our adjustable arterial coupler to improve vessel compatibility and reduce dysfunction. Next steps include studying flow-mediated dilation, stretch responses, and molecular signaling to optimize our stent/cuff design.

2025/09/11 - Overview of Sutureless Vascular Anastomosis: Technologies and Applications

ARSHIYA CHUGH - Sep 11, 2025, 4:24 PM CDT

Title: Overview of Sutureless Vascular Anastomosis: Technologies, Applications, and Research Opportunities

Date: 9/11/2025

Content by: Arshiya (Ria) Chugh

Present: N/A

Goals: Understand the different sutureless vascular anastomosis technologies, their advantages and limitations, and current clinical applications. Also identify gaps in the field that could guide future research or device improvements.

Content:

Sutureless Vascular Anastomosis

- Vascular anastomosis: Surgical connection of blood vessels; used in vascular, reconstructive, and transplant surgery.
- Traditional method: Handsewn sutures (Carrel triangulation method, 1902)
- Pros: Established technique, high success rates
- Cons: Requires training, long operative time, technical complications
- Sutureless methods: Developed to simplify procedure, reduce operative time, and maintain vessel patency.

Types of Sutureless Vascular Anastomosis Technologies

Stents / Stent-Grafts / Grafts

- Provide structural support to vessels
- Materials: Stainless steel, nitinol, titanium, PTFE, Dacron
- Used in: CABG, aortic bypass, peripheral revascularization
- Pros: Fast, less blood loss, compatible with variable diameters, works with atherosclerotic vessels
- Cons: Foreign body, thrombosis, intimal hyperplasia, stenosis

Couplers

- Evert vessels and connect via interlocking rings with pins
- Common in: Free-tissue transfer, breast, head & neck reconstruction
- Pros: Fast, good strength, less expertise needed
- Cons: Requires skilled assistant, vessel trauma risk, specific vessel diameter

Mechanical Connectors / Clips / Magnets / Staplers

- Provide mechanical support for anastomosis
- Pros: Reduced operative time, easier for non-specialists, potential robotic use
- Cons: Stenosis, vessel mismatch, reduced compliance, foreign body response

Chemical Devices

Lasers

- Fuse vessels via heat-induced collagen fusion (70–80°C)

- Types: CO2, diode (Nd:YAG, Ho:YAG), excimer, argon
- Pros: High patency, precise, feasible for very small vessels (<0.5 mm)
- Cons: Leakage, thrombosis, aneurysm risk, long prep/operating time

Adhesives

- Bond vessels chemically without sutures
- Pros: Fast, less needle trauma, adjunct to increase strength
- Cons: Inflammatory response, thrombosis, stenosis, lower tensile strength

Study & Patent Landscape

- Literature: 211 studies
- Mostly in vivo animal studies (n=193), some human trials (n=68)
- Patents: 475 technologies, only 17.9% FDA approved (n=85)
- Most common patented technologies: Adhesives (n=103), stents/stent-grafts (n=68), mechanical connectors (n=61)

Common Advantages

- Faster procedure & operating time
- Less need for surgical expertise
- Reduced vessel trauma
- Greater reproducibility and anastomotic strength
- Some can act as drug-delivery platforms

Common Disadvantages

- Reduced vessel compliance
- Thrombosis, stenosis, leakage
- Foreign body reaction
- Device cost
- Limited long-term data beyond 6 months

Clinical Adoption

- Couplers: Widely used in human microsurgery (free-flap transfer)
- Stents/Stent-Grafts/Grafts: Mostly animal studies; limited human use
- Lasers: Rarely used in humans; SELANA had a fatal complication limiting clinical trials
- Regulatory hurdles: FDA approval is costly and time-consuming (Premarket: ~$94M, 7 years; 510(k): ~$31M)

Takeaways

- Sutureless vascular anastomosis reduces procedure time and expertise needed.
- Mechanical devices are structurally stronger but have foreign body risks.
- Chemical devices avoid foreign material but may have lower strength or risk strictures.
- Long-term efficacy and market adoption remain limited.
- Future research: Standardization, surgeon-focused design, regulatory approvals, long-term outcomes.

[1] D. P. Mallela *et al.*, “A systematic review of sutureless vascular anastomosis technologies,” *Seminars in Vascular Surgery*, vol. 34, no. 4, pp. 247–259, Oct. 2021, doi: https://doi.org/10.1053/j.semvascsurg.2021.10.004.

Conclusions/action items: The article provides valuable insights into sutureless vascular connections, which can inform the design of an adjustable stent/cuff for arterial anastomosis. Key takeaways include understanding different connection techniques and potential challenges in achieving secure, efficient attachments. Apply these insights to the project and evaluate its effectiveness in improving surgical outcomes.

2025/09/23 - Hemodynamic Significance of Coronary Narrowing Length - Product Design Specification

ARSHIYA CHUGH - Sep 23, 2025, 8:34 PM CDT

Title: Hemodynamic Significance of Coronary Narrowing Length

Date: 9/23/2025

Content by: Arshiya (Ria) Chugh

Present: N/A

Goals: Understand how lesion length influences hemodynamics, beyond diameter alone.

Content:

Key Concepts:

- Arterial narrowing is typically described by percentage stenosis.
- This study emphasizes that *length* of narrowing also affects pressure gradient and flow.
- Longer narrowings increase resistance disproportionately compared to shorter ones.

Methods & Approach:

- Measured hemodynamics across coronary arteries with varying lesion lengths.

Key Findings:

- Lesion length independently worsened flow reduction.
- Both diameter and length determine clinical significance of stenosis.

Clinical/Pathological Implications:

- Device placement must consider not just diameter but also axial length of narrowing.
- Ignoring length could underestimate functional severity.

Relevance to Arterial Coupler Redesign:

- Coupler designs must minimize added length to avoid creating hemodynamically significant narrowings.
- Geometry should allow smooth flow transition across junction.
- Reinforces importance of optimizing lumen shape, not just size.

[1] R. L. Feldman, W. W. Nichols, C. J. Pepine, and C. R. Conti, “Hemodynamic significance of the length of a coronary arterial narrowing,” Am. J. Cardiol., vol. 41, no. 5, pp. 865–871, May 1978, doi: 10.1016/0002-9149(78)90726-9.

Conclusions/action items: Lesion length is a critical variable in vascular flow. Our coupler should aim for minimal axial footprint and smooth lumen continuity. Potential next step could include CFD modeling of flow through prototype coupler.

2025/09/23 - The Science of Anastomotic Healing - Product Design Specification

ARSHIYA CHUGH - Sep 23, 2025, 9:03 PM CDT

Title: The Science of Anastomotic Healing

Date: 9/23/2025

Content by: Arshiya (Ria) Chugh

Present: N/A

Goals: Understand the biological processes governing anastomotic healing, including phases of repair, risk factors for failure, and implications for device design.

Content:

Key Concepts:

- Anastomotic healing involves coordinated biological processes: inflammation, proliferation, and remodeling.
- Healing depends on vascular perfusion, tissue oxygenation, and cellular signaling at the anastomotic site.
- Disruption in healing can lead to leakage, stenosis, or thrombosis.

Phases of Healing:

1. Inflammatory Phase: Platelet aggregation and clot formation create a provisional matrix; inflammatory cells clear debris.
2. Proliferative Phase: Fibroblasts and endothelial cells drive angiogenesis and extracellular matrix (ECM) deposition.
3. Remodeling Phase: Collagen crosslinking strengthens tissue; vascular structures mature.

Risk Factors for Failure:

- Local ischemia from poor perfusion.
- Systemic factors: malnutrition, diabetes, immunosuppression.
- Mechanical stress at the junction (e.g., high tension, mismatch in geometry).

Clinical/Pathological Implications:

- Anastomotic leaks are major causes of morbidity/mortality in vascular and gastrointestinal surgery.
- Successful healing requires balance between mechanical stability and biological integration.

Relevance to Arterial Coupler Redesign:

- Device must avoid impairing blood supply to the anastomotic site.
- Coupler should minimize local ischemia and allow for proper cellular infiltration.
- Material and geometry should promote ECM deposition and remodeling without excessive fibrosis.

[1] R. B. Morgan and B. D. Shogan, “The science of anastomotic healing,” Semin. Colon Rectal Surg., vol. 33, no. 2, p. 100879, June 2022, doi: 10.1016/j.scrs.2022.100879.

Conclusions/action items: Anastomotic healing is multifactorial, requiring perfusion, ECM remodeling, and controlled inflammation. Our coupler must preserve blood flow, reduce mechanical stress, and support natural healing processes. Next step: investigate how different materials and designs affect

fibroblast and endothelial cell responses at the junction.

2025/09/11 - Research on the Microvascular Anastomotic Coupler as a Competing Design

ARSHIYA CHUGH - Sep 11, 2025, 5:01 PM CDT

Title: Research on the Microvascular Anastomotic Coupler as a Competing Design

Date: 9/11/2025

Content by: Arshiya (Ria) Chugh

Present: N/A

Goals: Analyze insights from this competing device to guide potential improvements, differentiation, and design considerations for our own arterial coupler project.

Content:

Product: Microvascular Anastomotic Coupler System

Purpose: Device for fast, sutureless microvascular anastomosis (arteries & veins).

Indications for Use**:**

- Peripheral vascular system only.
- Vessel diameters: 0.8 mm – 4.3 mm.
- Vessel wall thickness: ≤ 0.5 mm.
- Vessel size measured with gauge for proper device selection.

Key Features & Benefits**:**

- Intima-to-intima contact → no intraluminal suture material → lower thrombosis risk.
- Versatile → handles vessel size mismatches.
- Usable in both end-to-end and end-to-side configurations.
- Simplicity & dependability → quicker procedure time compared to sutures.

Limitations

- Mostly used for veins, not arteries (arterial walls are stiffer and thicker).
- Limited for vessels >4 mm or <1 mm.
- Rigid rings → may cause mismatch with compliance of natural vessel wall.
- Can be bulky in small operative fields.

Other Notes:

- Rx only (requires physician oversight).
- IFU must be consulted before use.
- Developed for microsurgical procedures (not for central or large vessels).

[1] “Microvascular Anastomotic Coupler | Microvascular Anastomosis Couplers,” *Synovismicro.com*, 2020. https://www.synovismicro.com/html/products/gem_microvascular_anastomotic_coupler.html? (accessed Sep. 11, 2025).

Conclusions/action items: Potential improvement: more flexible cuff/stent design to handle circumferential stretch and maintain physiologic shear stress. GEM coupler shows feasibility of sutureless systems but is not adjustable. Redesign could focus on compliance, adaptability to artery mechanics, and minimizing shear stress disturbances.

2025/10/15 - ISO 25539-2:2020 Endovascular Devices and Vascular Stents

ARSHIYA CHUGH - Dec 09, 2025, 2:05 PM CST

Title: ISO 25539-2:2020 Endovascular Devices and Vascular Stents

Date: 10/15/25

Content by: Arshiya Chugh

Present: N/A

Goals: Summarize key requirements of ISO 25539-2:2020 relevant to vascular implant safety and performance. Identify which testing domains apply to our arterial coupler/stent-like prototype. Determine implications for future verification and validation planning.

Content:

ISO 25539-2:2020 is the global standard governing non-active endovascular devices, specifically vascular stents and stent-grafts intended to maintain or restore patency in the cardiovascular system. The standard outlines a structured framework for preclinical evaluation, including mechanical testing, fatigue performance, dimensional requirements, biocompatibility, and in vitro and in vivo assessments necessary to demonstrate device safety.

Key sections include:

1. Design and Material Requirements

The standard mandates clear justification for material selection, corrosion resistance, fatigue durability, and surface finish. It emphasizes the need to evaluate both bulk properties and surface characteristics that affect thrombogenicity and endothelialization—directly relevant to our exploration of nitinol and laser-textured surfaces.

2. Dimensional and Integrity Verification

Stents must meet strict tolerances regarding diameter, length, radial stiffness, and structural uniformity. For coupler-type devices, analogous dimensional verification would apply to lumen patency, wall thickness, and feature repeatability.

3. Mechanical Testing Requirements

ISO 25539-2 specifies a set of minimum mechanical evaluations, including:

Radial force and chronic outward force

Flexibility and kink resistance

Fatigue durability under pulsatile flow conditions

Corrosion testing for metallic devices

These requirements directly inform what future testing will be needed once our nitinol prototype advances beyond feasibility. Fatigue testing is especially critical given arterial cyclic loading.

4. Deployment and Delivery System Evaluation

For stents, delivery systems must be tested for trackability, pushability, recapture performance, and deployment accuracy. Although our arterial coupler is not catheter-delivered in its current form, future iterations may integrate minimally invasive deployment, making these provisions potentially relevant.

5. Biological and Hemocompatibility Requirements

The standard references ISO 10993 for biocompatibility testing and additionally requires assessment of:

Thrombogenicity

Endothelialization potential

Hemolysis

Particulate generation during deployment

These criteria align with our interest in surface engineering (e.g., microgrooves, oxide control) to reduce platelet adhesion and promote vessel healing.

6. In Vitro and In Vivo Performance Testing

Bench testing must simulate physiologic loading, vessel deformation, and flow environments. In vivo evaluation must characterize local tissue response, neointimal proliferation, luminal patency, and degradation behavior for absorbable devices.

These elements provide a roadmap for future validation steps once the coupler transitions from conceptual prototype to a regulated medical device framework.

[1] *Iso.org*, 2023. https://www.iso.org/obp/ui/en/#iso:std:iso:25539:-2:ed-3:v1:en

Conclusions/action items: Use ISO 25539-2:2020 as a guiding framework for defining next-semester testing (radial force, fatigue, corrosion, particulate characterization). Begin mapping which portions apply directly to our design versus which apply only to catheterized deployment systems. Integrate ISO 10993 and ISO 25539-2 hemocompatibility expectations into future surface engineering decisions.

2025/10/25 - Material Classes for Stent Design and Their Mechanical & Biological Tradeoffs

ARSHIYA CHUGH - Dec 09, 2025, 1:59 PM CST

Title: Material Classes for Stent Design and Their Mechanical/Biological Tradeoffs

Date: 10/25/25

Content by: Arshiya (Ria) Chugh

Present: N/A

Goals: Summarize the major stent material classes (metallic, polymeric, biodegradable). Identify mechanical, biological, and manufacturability considerations relevant to vascular implants. Extract material design principles applicable to future iterations of our arterial coupler.

Content:

Stent materials span three primary categories—permanent metals, permanent polymers, and fully biodegradable metals or polymers—each selected to balance mechanical performance, deliverability, and hemocompatibility.

Metallic stents (316L stainless steel, cobalt-chromium alloys, nitinol, platinum-iridium, tantalum) provide high radial strength, radiopacity, and reliable crimping or self-expansion. Balloon-expandable alloys such as 316L or CoCr offer plastic deformation for deployment, whereas nitinol provides superelastic self-expansion. Limitations include restenosis, chronic inflammation from metallic ions, and rigid mechanical mismatch with native arteries. Nitinol's elasticity and fatigue resistance make it attractive for tortuous vessels, but its nickel content remains a persistent biocompatibility concern.

Biodegradable metals, primarily magnesium and iron alloys, aim to provide temporary scaffolding and then resorb. Magnesium-based stents demonstrate favorable hemocompatibility and encourage endothelialization but degrade rapidly, risking early loss of support. Iron-based stents degrade more slowly and show reduced SMC proliferation but may persist too long in vivo. Both material types must balance corrosion rate with radial strength retention—key considerations for applications requiring short-term structural alignment, as in anastomosis devices.

Polymeric stents (PLLA, PLGA, PDLLA, tyrosine-derived polycarbonates) offer bioabsorption, eliminating long-term implant complications. However, polymer stents often experience high recoil, lower radial strength, brittle fracture during deployment, and thicker strut requirements. Their degradation products may also induce inflammatory responses depending on molecular weight and crystallinity. Surface coatings—drug-eluting polymers, inorganic films, or hydrophilic/hydrophobic blends—are commonly employed to improve hemocompatibility and reduce thrombosis.

Advances in **surface modification** allow decoupling of bulk mechanical properties from blood-contacting performance. Plasma-based methods, polymer coatings, and laser texturing (e.g., grooves, nanostructures) address platelet adhesion, endothelialization, and corrosion resistance. The interaction between surface chemistry, oxide stability, surface energy, and microtexture strongly influences thrombogenicity and neointimal hyperplasia. This is particularly relevant for next-generation stents aiming to promote rapid surface endothelialization without anti-proliferative drugs.

For our arterial coupler design, understanding these material trends reinforces several considerations: nitinol offers conformability and high fatigue resistance; stainless steel or CoCr provide manufacturability and strength; and biodegradable materials demonstrate potential for temporary vascular support if corrosion kinetics can be controlled. Surface engineering—including microgrooving or controlled oxide formation—appears critical for optimizing hemocompatibility, particularly at the blood-contacting interface of a vascular anastomosis device.

[1] "Stent Material - an overview | ScienceDirect Topics," *www.sciencedirect.com*. https://www.sciencedirect.com/topics/engineering/stent-material

Conclusions/action items: Consider nitinol or CoCr as candidate materials for future prototypes requiring elastic deformation or thin-walled strength. Evaluate polymer–metal hybrid strategies only if long-term implant permanence is undesirable. Incorporate laser-based or plasma surface treatments into future work to modulate endothelial response and reduce thrombogenicity.

2025/10/07 - Fatigue Analysis of Nitinol Stents Under Walking-Induced Femoropopliteal Motion

ARSHIYA CHUGH - Oct 07, 2025, 8:45 PM CDT

Title: A Computational Study of Fatigue Resistance of Nitinol Stents Subjected to Walk-Induced Femoropopliteal Artery Motion

Date: 10/72025

Content by: Arshiya (Ria) Chugh

Present: N/A

Goals: To understand how walking-induced arterial motion affects the fatigue behavior of self-expanding nitinol stents in the femoropopliteal artery, using finite element (FE) modeling to simulate realistic loading conditions and identify primary factors contributing to fatigue failure.

Content:

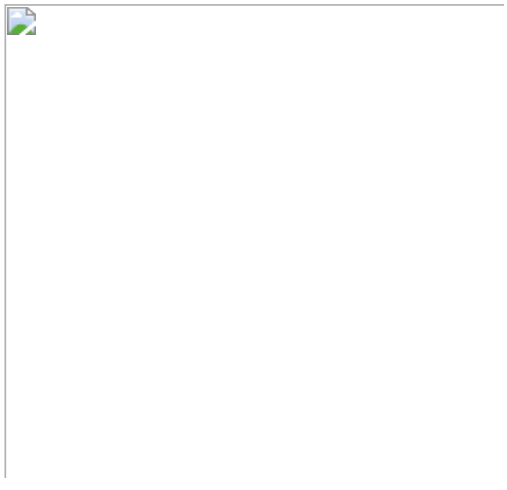
Peripheral artery disease (PAD) often occurs in the femoropopliteal arteries and is commonly treated using self-expanding nitinol stents due to their flexibility and superelasticity. However, clinical studies have shown frequent stent fractures, attributed to the complex, repetitive biomechanical environment in the leg during daily motion.

This study developed advanced FE models of a diseased artery with plaque, layered arterial wall, and a Zilver Flex® nitinol stent. The simulation process replicated angioplasty, crimping, self-expansion, and cyclic deformations under conditions mimicking walking-induced bending, torsion, and axial compression. Material properties were modeled using hyperelastic and superelastic constitutive laws to capture realistic tissue and nitinol behavior.

Results demonstrated that pulsatile blood pressure alone did not cause fatigue failure, whereas combined mechanical loads—especially bending significantly increased strain and fatigue risk. Among the three motion types, bending contributed most to fatigue damage, followed by axial compression and torsion. Under combined loading, some stent regions exceeded the fatigue strain limit, indicating a high likelihood of fracture. The highest strain concentrations occurred at the inner corners of stent U-bends.

The findings emphasize that walking motion produces the most critical loading scenario for implanted nitinol stents, reinforcing the need to consider patient-specific arterial motion in stent design and placement.

This study demonstrated localized areas of high strain at the inner bends of the stent geometry where peak effective strain reached approximately 3.73% during bending. These findings confirm that bending contributes most to fatigue risk, where strain amplitudes under pulsatile loading remain below the fatigue strain limit.



lustrating fatigue behavior of nitinol under simulated bending.

ł. Willcock, “A computational study of fatigue resistance of nitinol stents subjected to walk-induced
, vol. 118, p. 110295, Mar. 2021, doi: https://doi.org/10.1016/j.jbiomech.2021.110295.

ctor driving nitinol stent fatigue during walking. Pulsatile blood pressure contributes minimally to
ompression, torsion) yield the highest risk of fracture. Future research should incorporate patient-specific artery geometries and plaque morphologies for improved fatigue prediction.

2025/11/21 - Review of PTFE Laser-Cut Vascular Coupling Device

ARSHIYA CHUGH - Dec 09, 2025, 1:45 PM CST

Title: Analysis of Laser-Cut PTFE Vascular Coupling Device as Benchmark for Anastomosis Performance

Date: 11/21/25

Content by: Arshiya Chugh

Present: N/A

Goals: Summarize key findings from the PTFE vascular coupling device (VCD) study. Identify performance metrics relevant to our rigid tubing feasibility testing. Translate design principles and testing approaches from the study to our arterial stent/coupler development.

Content:

The reviewed article presents a laser-cut vascular coupling device (VCD) fabricated from PTFE with diameters ranging from 1.5–7 mm, designed to accelerate and simplify end-to-end anastomosis in reconstructive and trauma surgery. The VCD aims to reduce operative time, improve consistency, and avoid foreign material exposure to the bloodstream by achieving intima-to-intima contact—an important benchmark for evaluating our own adjustable stent/coupler concept.

A central feature of the VCD design is a hinged wing system with stainless-steel spikes that secure the vessel wall at a controlled 45° angle before eversion. This geometry facilitates consistent vessel mounting while minimizing trauma, providing insight into the level of structural support required for reliable inversion during our rigid tubing experiments. The associated tool set demonstrates how guided, constrained motion can reduce variability in micro-anastomosis—reinforcing the need for geometric repeatability during our feasibility testing.

Mechanical and flow tests from the study showed:

- Anastomosis time reduced to ~5 minutes, far faster than hand suturing.
- Tensile separation strength of ~20 ± 4 N, significantly exceeding physiologic loads (~0.17 N).
- No leakage under pressurized flow (160–360 mmHg) and no detectable lumen constriction.
- Micro-CT and histology confirmed maintained patency and vessel alignment.

These outcomes provide valuable reference points for our testing. Specifically, the inversion behavior and lumen preservation demonstrated in the VCD trials underscore the importance of using correctly scaled rigid tubing lengths (3 mm) to replicate vessel alignment without causing strain or collapse—directly validating the adjustments we made after our 11/19 and 11/24 client testing sessions.

Additionally, the article's fabrication method—multi-layer CO_2 laser cutting of PTFE with 20 µm hinges—supports the feasibility of applying micro-scale laser machining or lithography techniques to future iterations of our nitinol prototype. The study reinforces that hinge-based or compliant mechanisms can be manufactured at sub-millimeter scales and still achieve repeatable deformation behavior.

[1] C. Gehrke, H. Li, H. Sant, B. Gale, and J. Agarwal, "Design, fabrication and testing of a novel vascular coupling device," *Biomedical Microdevices*, vol. 16, no. 1, pp. 173–180, Sep. 2013, doi: https://doi.org/10.1007/s10544-013-9819-z.

Conclusions/action items: Compare our tubing inversion success to the controlled 45° mounting achieved in the study to justify 3 mm prototype height. Use mechanical performance (tensile strength and leak-free sealing) as performance targets for future nitinol prototypes. Continue investigating micron-scale laser machining approaches, informed by the fabrication methods demonstrated in the PTFE VCD.

2025/12/03 - Impact of Laser-Based Surface Engineering on Stent Performance

ARSHIYA CHUGH - Dec 09, 2025, 1:49 PM CST

Title: Impact of Laser-Based Surface Engineering on Stent Performance

Date: 12/3/25

Content by: Arshiya Chugh

Present: N/A

Goals: Review laser-based surface engineering and its relevance to next-generation stent design. Identify texture and chemistry modifications that influence endothelialization, SMC behavior, thrombosis, and restenosis. Determine how micro- and nano-scale laser texturing could inform future iterations of our prototype.

Content:

This review article summarizes recent advancements in laser-based surface modification of cardiovascular stents, addressing clinical challenges such as late-stent thrombosis (LST) and in-stent restenosis (ISR). Conventional surface treatments (sandblasting, chemical etching, plasma) lack precision or introduce harmful residues, whereas laser surface engineering offers high resolution, selective material removal, and controllable chemistry modification essential for biomedical microdevices.

Laser processes—including laser texturing, direct laser interference patterning (DLIP), and laser-induced periodic surface structures (LIPSS)—enable fabrication of grooves, nanopillars, porous structures, nanowires, and freeform geometries across nano- to micron-scale ranges. These engineered surfaces significantly affect vascular cell behavior:

- **Endothelial Cells (ECs):** Enhanced adhesion, migration, and proliferation on nano-roughened or finely grooved surfaces, promoting rapid endothelialization.
- **Smooth Muscle Cells (SMCs):** Certain microgroove patterns inhibit SMC proliferation and shift them toward a more contractile phenotype, decreasing neointimal hyperplasia and restenosis risk.
- **Platelets:** Nanoscale surface roughness can reduce platelet adhesion and activation—critical for minimizing thrombosis during early post-implantation.
- **Polymeric/Bioresorbable Stents:** Laser modification slows degradation rate, improves mechanical stability, and reduces inflammatory response.

For metallic stent materials (e.g., stainless steel, nitinol), laser-based engineering offers additional advantages:

- High precision on **curved surfaces**, compatible with small-diameter arterial stents.
- Ability to modify **surface chemistry** (nitridation, oxidation, DLC coatings) to improve biocompatibility.
- Capability to generate **hierarchical structures** that combine topography + chemistry for synergistic biological effects.

These findings are highly relevant to our project, particularly as we explore miniaturized prototypes and consider nitinol fabrication for next semester. Laser micro-texturing could be integrated post-manufacture to improve **patency**, reduce **platelet adhesion**, and guide **endothelial regrowth** along the luminal interface. Additionally, the review supports investigating micron-scale lithography and laser micromachining in future phases, aligning with our earlier exploration into laser microfabrication for stent geometries.

[1] J. Dong, M. Pacella, Y. Liu, and L. Zhao, “Surface engineering and the application of laser-based processes to stents - A review of the latest development,” *Bioactive Materials*, vol. 10, pp. 159–184, Apr. 2022, doi: https://doi.org/10.1016/j.bioactmat.2021.08.023.

Conclusions/action items: Consider laser-based micro-texturing (grooves or nanopillars) for future nitinol prototypes to promote endothelialization and reduce platelet adhesion. Evaluate the feasibility of laser-induced periodic surface structures (LIPSS) for fine control of luminal roughness. Explore vendors capable of DLIP or ultrafast laser micromachining for small-diameter vascular devices.

2025/12/04 - Impact of Laser-Textured Microgrooves and Sidewall Edge Structuring on Endothelialization

ARSHIYA CHUGH - Dec 09, 2025, 1:53 PM CST

Title: Impact of Laser-Textured Microgrooves and Sidewall Edge Structuring on Endothelialization

Date: 12/4/25

Content by: Arshiya Chugh

Present: N/A

Goals: Summarize the key findings of the 2025 study on laser-textured CoCr stents. Identify surface engineering strategies that improve endothelialization and reduce thrombosis. Translate the study's microstructural design principles to future iterations of our adjustable arterial coupler.

Content:

This study investigated a novel micro-hierarchical surface modification strategy applied to cobalt-chromium (CoCr) coronary stents, using precise laser texturing to fabricate microgrooves (5–30 μm) integrated with **sidewall edge structures**. These features produced interconnected "grid-like" microchannels designed to accelerate endothelialization and reduce platelet adhesion—two major determinants of stent healing and long-term patency.

Laser fabrication enabled highly controlled grooves and extended sidewall edges capable of guiding **rat aortic endothelial cell (RAEC)** adhesion, proliferation, and migration. The most significant findings include:

- **~6× increase in EC viability** on 5 μm microgroove grids vs. non-patterned surfaces by day 3.
- **Enhanced EC attachment at groove intersections and sidewalls**, which act as "anchoring channels" guiding directional cell spreading.
- **Steep groove edge angles (~63°)** produced the highest cell densities, demonstrating the importance of microstructure geometry in accelerating endothelial coverage.
- **Substantially reduced platelet deposition** on grid-patterned surfaces, confirmed by LDH assay and SEM imaging, indicating improved hemocompatibility.
- **Mechanical testing (three-point bending and radial compression)** showed **no significant loss of flexibility or radial strength**, suggesting that laser texturing preserves essential stent mechanical integrity.

The study demonstrates that microgroove patterns and engineered sidewall edges provide both mechanical and biochemical guidance cues, dramatically improving biocompatibility without relying on drug-eluting coatings. For our project, this suggests potential future strategies for fine-scale surface texturing on nitinol or stainless-steel prototypes to enhance biological integration.

These findings also validate the relevance of **micron-level patterning** (5–10 μm scale) as a feasible and effective design dimension—aligning with our exploration of micro-laser lithography for next-semester prototyping. The ability to engrave consistent features along **curved stent struts** directly supports the potential manufacturability of similar features on our eventual stent-based anastomosis device.

[1] M. S. Ibrahim *et al.*, "Novel Laser-Textured Grooves Extended to the Sidewall Edges of CoCr Surfaces for Rapid and Selective Endothelialization Following Coronary Artery Stenting," *Biomaterials*, p. 123299, Mar. 2025, doi: https://doi.org/10.1016/j.biomaterials.2025.123299.

Conclusions/action items: Consider integrating **5–10 μm microgrooves** and **steep sidewall geometries** into future nitinol prototypes to improve endothelialization. Explore ultrafast laser fabrication vendors capable of producing hierarchical patterns on curved, small-diameter devices. Investigate the potential to apply similar texturing only to the luminal surface of our coupler to reduce thrombogenic risk.

2025/10/07 - Design Ideas for Arterial Coupler Re-Design

ARSHIYA CHUGH - Oct 07, 2025, 8:34 PM CDT

Title: Design Ideas for Arterial Coupler Re-Design

Date: 10/7/2025

Content by: Arshiya (Ria) Chugh

Present: N/A

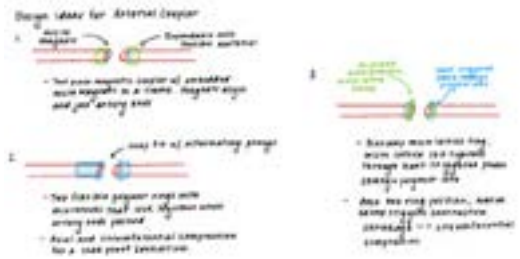
Goals: Develop and refine preliminary design concepts to include in the design matrix.

Content:

Refer to the attached document for detailed design ideas and corresponding specifications.

Conclusions/action items: Review and discuss proposed design concepts with the team. Select the final design collaboratively. Update and revise the design matrix based on team decisions.

ARSHIYA CHUGH - Oct 07, 2025, 8:35 PM CDT



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Design_Ideas.pdf (456 kB)

2025/10/24 - MATLAB Training On-Ramp Course Completion

ARSHIYA CHUGH - Oct 26, 2025, 3:12 PM CDT

Title: MATLAB Training On-Ramp Course Completion

Date: 2/20/2024 (Training completed prior to today)

Content by: Arshiya (Ria) Chugh

Present: N/A

Goals: Complete MATLAB training in order to utilize this tool later in the semester for various purpose.

Content:

See attached document for certification.

Conclusions/action items: Continue to develop skills on MATLAB. Brainstorm future ways to analyze data using this program. Understand statistical anaylsis.

ARSHIYA CHUGH - Feb 20, 2024, 1:28 PM CST

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certificate.pdf (355 kB)

2025/10/24 - Intro to Machining Certification

ARSHIYA CHUGH - Oct 26, 2025, 3:12 PM CDT

Title: Intro to Machining Training (Green Permit) Completion Certification

Date: 10/24/2025 (Training completed prior to today)

Content by: Arshiya (Ria) Chugh

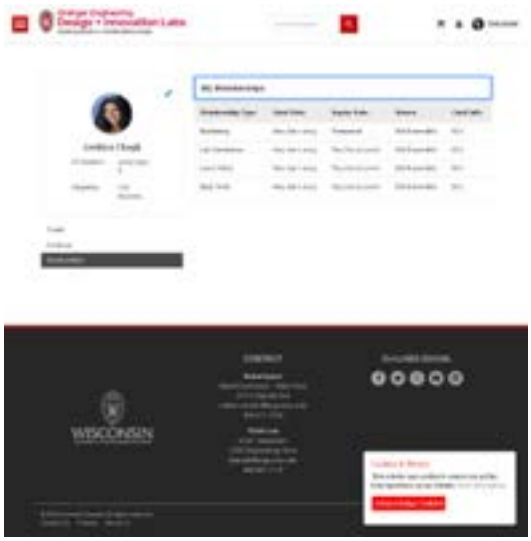
Present: N/A

Goals: Complete intro to machining training in order to fabricate sample holder.

Content: See attached document for certification.

Conclusions/action items: Exercise safety and knowledge in team lab. Consult with TEAM Lab regarding stent design and printing methods. Schedule design consultation with Jesse Darley.

ARSHIYA CHUGH - Mar 18, 2024, 8:13 PM CDT



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Profile_-_Grainger_Engineering_-_UW_Madison.pdf (156 kB)

2025/10/24 - Updated Safety Trainings for BME 400

ARSHIYA CHUGH - Oct 24, 2025, 7:52 PM CDT

Title: Safety Trainings for BME 400

Date: 10/24/2025

Content by: Arshiya (Ria) Chugh

Present: N/A

Goals: Partcipate in additional trainings for design semester.

Content:

Refer to the attached document for proof of completion/

Conclusions/action items: Continue trainings and integration into design semester. Work with team to design preliminary prototype. Develop testing protocols.

ARSHIYA CHUGH - Oct 24, 2025, 7:52 PM CDT

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BME_400_Training_Documentation.png (189 kB)

2025/09/16 - Cardiovascular Stents (Materials Research)

Daniel Pies - Dec 02, 2025, 2:03 PM CST

Title: Cardiovascular Stents: A Review of Past, Current, and Emerging Devices

Date: 9/16/2025

Content by: Daniel

Present: n/a

Goals: Take notes on this article with the intent of establish baseline knowledge of biomaterials commonly used in stent/anastomosis procedures.

Content:

- Recoil Diameter- the percent decrease of stent diameter between its expanded and relaxed forms
  - Stent materials must have adequate mechanical properties to avoid significant changes in their dimensions
- Common manufacturing technique is laser cutting, however nitinol has also been processed into stents using thin-film technology followed by a photoetching step
- Ideal Properties of Stents (these would also apply to arterial recouplers)
  - Biocompatibility, flexibility, deliverability, low rates of thrombogenesis, low neointimal hyperplasia, minimal trauma to vessel wall, minimal inflammatory reaction, good re-reendothelialization,
  - Maybe consider: strong radial force, good radiopacity (visualization under fluoroscopy), appropriate drug release, scaffolding for vessel

Table 1.

Mechanical properties of the most common stent metals and alloys.

Stent Material	Young's Modulus (GPa)	Ultimate Tensile Strength (MPa)	Equivalent Von-Mises Stress (MPa)	Elongation at Break (%)	References
Iron	211	270	-	40	[33,37,38,39]
Stainless steel	193	595	231.14	40	[15,33]
Tantalum	186	285	514.70	-	[15,40]
Nitinol	45–50	1200	436.12	~20	[15,41]
Cobalt-chromium L-605	243	1020	536.20	50	[15,42]
Cobalt-chromium MP35 N	233	930	529.82	45	[15,42]

- Table of Common Materials and their properties

Bare-Metal Stents (BMSs)

- Stainless (316L) is resistant, hard, and non-corrosive, however limited biocompatibility is a major drawback due to thrombosis
- Co-Cr alloys are corrosion resistant, strong radial force, better radiopacity, allows for thinner struts
- Pt-Ir - corrosion resistant
- Tantalum - good mechanical properties, biologically inert, lacks ferromagnetism, very stable and resistant, biocompatible oxide surface layer, limited biocompatibility
- Nitinol (Ni-Ti) shape memory alloy, better biocompatibility, nickel migration can cause immune response over time, self-expanding properties

Non-degradability leads to post-intervention complications (sub)acute occlusion, neointimal hyperplasia resulting in stenosis (due to both arterial damage and stent implantation), late-stage thrombosis, chronic inflammatory response.

Drug-Eluting Stents (DESs)

- Structure - metallic platform, coated with drug-eluting durable polymer
- Platform materials include Co-Cr or Pt-Cr alloys for reduced strut thickness, superior radial force, and radiopacity
- Coating Materials (Polymers)
    - Biodegradable polymers are preferred to mitigate inflammation and thrombosis risk
    - Must provide structure, consistent dosing, controlled release, non-toxic, encourage arterial healing
    - Examples: Phosphorylcholine, polylactic acid (PLA), poly(vinylidencefluoride-co-hexafluoropropenen), polyvinylpyrrolidone
- Drugs - Sirolimus, paclitaxel, zotarolimus, everolimus, novolimus

Bioresorbable Stents (BVSs) and Bioresorbable Polymeric Mateirals

- Fabricated from materials that provide transient support and progressively degrade, dissolving or absorbing into body after remodeling process
- Poly-L-Lactic Acid (PLLA): most typical biocompatible polymer for current BVS, used in the first European Medicines Agency-approved BVS
- Polylactic Acid (PLA) - degradation 18-30 months
- Poly-DL-lactic acid (PDLLA): degradation 3-4 months
- Polyglycolide
- Other - PDLGA, PLGA, PCL, PLA/PCL (70/30 blend), PC, polyorthoesters

Bioresorbable Metallic Materials

- Mg alloys - superior elastic moduli and tensile strengths, uniform degradation, electronegative charge during degradation provides antithrombogenic potential, however often require polymer coatings to slow degradation and sustain drug delivery
    - AE21: Degradation 2-3 months
    - AE42
    - WE43
    - AZ31
- Iron alloys - well tolerated in vivo
- Zinc alloys

Bulk Metallic Glasses (BMGs)

- multi-component alloys with disordered atomic distribution
- Zr-based BMGs: excellent mechanical properties, high corrosion resistance, good biocompatibility, enhanced hardness and strength allow for thinner struts, reducing restenosis risk
    - Particularly investigated for self-expanding applications due to superior elastic spring-like restoration compared to nitinol

Shape Memory Polymers

ex: poly(tert-butyl acrylate), poly(ethylene glycol) dimethyl acrylate

light-responsive - could use some kind of "curing light" like they use at the dentist

cost effective, tunable, processability

Surface Modifications

- topographically creating nano- or micro- patterned surfaces, avoid platelet adhesion

- physiochemical modifications: generating functional groups or modulating surface energy using oxides, nitrides of metals, or deposition of metals/polymers

- Biofunctionalization: surface immobilization of biomolecules with specific biological properties to improve cell-material interactions

  - heparinization, CD31-mimetic peptides, biomarkers (CD146 antibodies), multifunctional coatings, superparamagentic iron oxide nanoparticles

Other Considerations

- Bioresorbable
  - Polymeric options: PLLA, PLA, PLGA, PGA, PCL
  - Metallic options: Mg alloys (AE21, AE42, WE43, AZ31), zinc alloys, iron alloys

Conclusions/action items:

This article just barely scrapes the surface of what is possible through combinations of manufacturing and material-selective processes. While this gives a good overview that may guide the initial choice, for example, knowing which class of material is appropriate (metal alloy, bulk metallic glasses, etc.), more in depth research will be needed before finalizing the design material. There are many diverse options that might be viable depending on exact goals.

Source:

[1] A. Scafa Udriște, A.-G. Niculescu, A. M. Grumezescu, and E. Bădilă, “Cardiovascular Stents: A Review of Past, Current, and Emerging Devices,” *Materials (Basel)*, vol. 14, no. 10, p. 2498, May 2021, doi: 10.3390/ma14102498.

2025/09/16- Systemic review of microvascular coupling devices for arterial anastomoses in free tissue transfer

Daniel Pies - Dec 02, 2025, 2:04 PM CST

Title: Systemic review of microvascular coupling devices for arterial anastomoses in free tissue transfer

Date: 9/16/2025

Content by: Daniel

Present: n/a

Goals: Take notes on this review to

Content:

Current Practice and Challenges for Arteries

- coupling devices are commonplace for venous anastomoses in microvascular free tissue transfer (FTT), however arterial anastomoses are still predominantly performed using traditional microvascular suture techniques
- couplers are not routinely used for arteries due to specific technical challenges

Historical Context

- first coupler - Nakayama et al. in 1962, featuring 2 metal rings with 12 interlocking pins/holes to anastomose vessel ends, later modified by Ostrup and Berggren in 1986

Feasibility and Success Rates

- Based on 15 retrospective case series and a total of 395 attempted arterial anastomoses, coupler use appears reasonably safe with a low rate of complications and good success rate, though based on low quality evidence
- Successful application rates varied: Chernichenko et al. reported 93.7% successful application in 127 cases, Assoumane et al. reported 100% success rate in 100 cases, and Spector et al. reported 77.5% success rate in 80 cases

Common Device and Material

- Most studies used 3M Unilink/Synovis Coupling Device
- One study by Daniel et al. notably used a novel absorbable coupling device made of polyglactin

Reasons for Conversion to Suture Technique

- coupling device was aborted and converted to hand-sewn technique in 8.4% of cases, though is a likely underreported metric
- Primary reasons for conversion included: thick-walled vessels, small-sized vessels, vessel size discrepancy, calcified stiff arterial walls, inadequate flow or diminished flow after eversion, inadequate vessel pliability, traumatic vessel tear, pseudoaneurysm formation
- Conversion leads to loss of critical vessel length and added surgical time

- These conversions need to be avoided at all costs

Observed Complications

- Thrombosis (1.9%)
- Rupture of anastomotic device (.3%)
- Mechanical failure (.5%) - due to a tear in the tunica intima while everting the vessel

Technical Challenges and Patient-Specific Factors

- Vessel pliability: arteries have increased thickness and elasticity compared to veins, making coupler placement technically challenging
- Atherosclerotic disease: significantly reduces pliability and increases risk for tears or ruptures, especially in older patients
- Fibrosis due to radiation therapy: can reduce arterial pliability and increase difficulty, and may cause intimal tears, particularly with thick walls
- Intimal Plaques or Calcifications: can increase manipulation difficulty
- Vessel size discrepancy: if the lumen size ratio between vessels exceeds 1:1.5, it may increase kinking and thrombosis
- Small diameter arteries: caution is advised, coupler sizes ranged from 1.0 to 4.0 mm,, with successful use reported in sizes as small as 1mm

Potential Advantages

- Decreased operation time: microvascular free flap cases are lengthy, and reduced surgical time is associated with better patient outcomes.
- improved maneuverability in difficult anatomic areas
- Improved tensile strength
- Better vessel eversion
- Decreased adventitial exposure (may reduce thrombosis risk compared to sutures)

Key implementations for team's design

- device must overcome challenge of manipulating thick-walled, less pliable, calcified, or small diameter arteries
- should facilitate reliable eversion of vessel walls without causing intimal tears
- significant reduction in anastomosis time compared to traditional suturing
- minimize adventitial exposure and contact with foreign material in lumen (reduce thrombosis risk)
- consider implications of patient age and comorbidities (eg. atherosclerosis, radiation effects, etc.) on the ease and safety of device application

Conclusions/action items:

The device designed must overcome the above listed challenges, namely facilitating the eversion of vessels and dealing with the much tougher arterial wall as compared to veins. Inspiration can be taken from similar designs, but should be innovated such that they overcome their associated challenges.

Source:

[1] A. R. Gundale, Y. J. Berkovic, P. Entezami, C.-A. O. Nathan, and B. A. Chang, “Systematic review of microvascular coupling devices for arterial anastomoses in free tissue transfer,” *Laryngoscope Investigative Otolaryngology*, vol. 5, no. 4, pp. 683–688, 2020, doi: 10.1002/lio2.427.

2025/09/18 - Experimental evaluation of microsurgical techniques in small artery anastomoses

Daniel Pies - Dec 02, 2025, 2:04 PM CST

Title: Experimental evaluation of microsurgical techniques in small artery anastomoses

Date: 9/18/2025

Content by: Daniel

Present: n/a

Goals: Take notes on this article with the intent of establish baseline knowledge of arterial anastomosis procedures.

Content:

1. Adventitial Stripping:
    1. Only minimal stripping of the adventitia (outer layer of fibrous tissue surrounding an organ) is indicated
        1. for artery or veins, this is called *tunica adventitia*
    2. excessive stripping should be avoided to prevent increased necrosis of the vessel ends at the anastomosis site
2. Suture Material and Needles:
    1. the best results in small vessel anastomoses are achieved using a 10-0 monofilament nylon suture material
    2. needles should be 75 micros or less in diameter
3. Suturing Technique (specifically for 1mm vessels)
    1. optimal anastomosis requires interrupted full thickness sutures
    2. this should be combined with minimal adventitial stripping
    3. it is crucial to use the smallest number of sutures possible
4. Perfusion of the Distal Lumina
    1. this specific study does not advocate routine perfusion of small arteries
    2. perfusion should only be performed when there are specific indications
        1. visible clot or debris inside the lumen cut
        2. evidence of sluggish or absent back-bleeding after vessel division
        3. spasm with intraluminal thrombus formation that won't clear on its own
        4. long ischemia time before anastomosis (higher risk of clot)
        5. suspected endothelial damage from handling, crushing, or adventitia stripping
        6. unequal caliber mismatch where turbulence or stagnant zones may predispose to clot formation

Conclusions/action items:

This study provides a fundamental basis for optimizing microsurgical techniques in small artery anastomoses, which is the target vessel size for this project. This research should be expanded on to further establish a baseline understanding of anastomosis procedures.

Source:

[1] J. R. Urbaniak, P. N. Soucacos, R. S. Adelaar, D. S. Bright, and L. A. Whitehurst, “Experimental evaluation of microsurgical techniques in small artery anastomoses,” *Orthop Clin North Am*, vol. 8, no. 2, pp. 249–263, Apr. 1977.

2025/09/24 - What is the Minimum Number of Sutures for Microvascular Anastomosis during Replantation

Daniel Pies - Dec 02, 2025, 2:04 PM CST

Title: What is the Minimum Number of Sutures for Microvascular Anastomosis during Replantation

Date: 9/24/2025

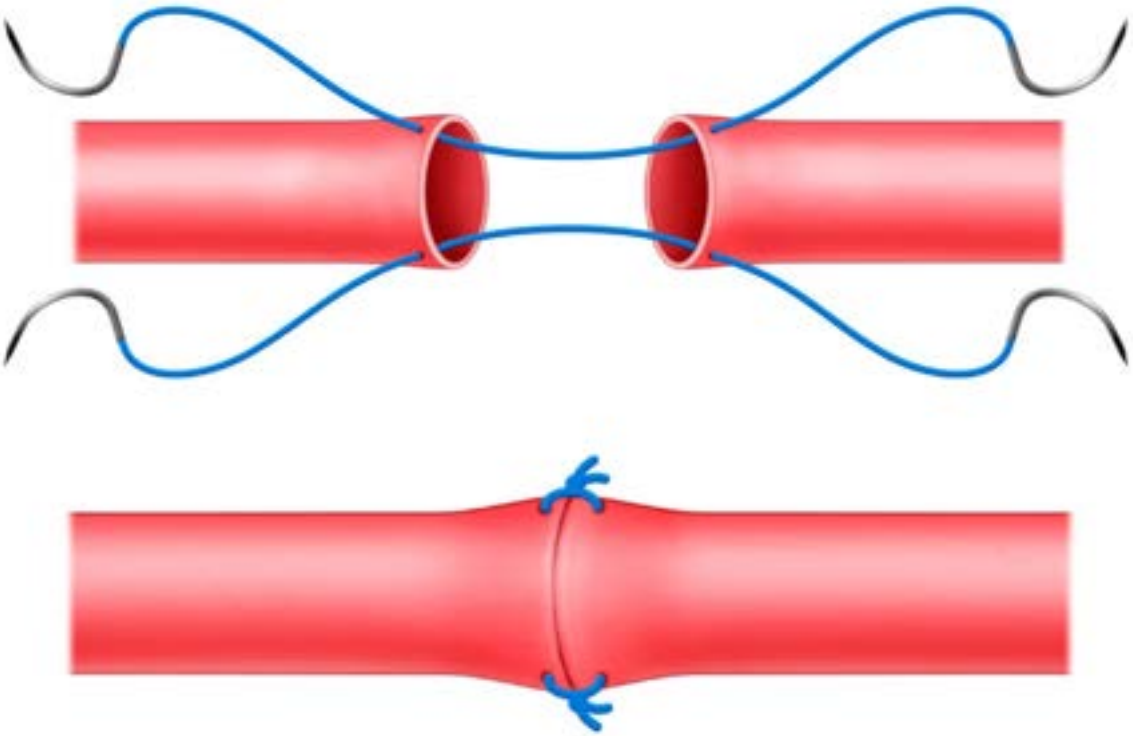
Content by: Daniel Pies

Present: n/a

Goals: Develop further understanding on the topic of sutures and how they connect within microvascular anastomosis procedures

Content:

- Vessel Size: this study focuses on arterial anastomosis in vessels with a diameter of less than .3mm during replantation, this is on the level of supermicrosurgery, so for the purpose of this paper, look just into the physical properties of sutures, not of the vessels themselves
- Problem: as vessel diameter decreases, reperfusion (restoring flow of blood to an organ or tissue) after anastomosis becomes more difficult. convention methods lead to two major challenges
    - vessel inner diameter becomes narrower due to the thickness of the suture material and number of sutures, leading to occlusion
    - high number of stitches is time-consuming and increases the ischemia time
- Authors of this paper attempted replantation using a 2-point suture technique to minimize complications, while ensuring lumen eversion
- 2-Point Suture Technique
    - their goal is to improve feasibility, speed, and reliability of reducing vascular occlusion complications caused by stitches (sutures)
    - while this study is focusing on supermicrosurgery (superfine tip forceps [11-0/12-0 sutures], it is still valuable for understanding the insufficiencies of current methods
- Procedure:
    - two stitches at 180 degree intervals
    - suture material was double arm 10-0 nylon suture



- the thread ran from the luminal side of the vessel outwards
  - this was to ensure the margins were successfully everted?
- if blood leakage persisted after the two initial sutures, additional suturing was performed in leaking areas

- Outcomes
  - with 21 cases of supermicrosurgery -
    - 2-Point group (12 cases): survival rate 91.7% (11/12), conversion to graft was 25%
    - 3/4-Point group (9 cases): survival rate 88.9% (8/9), conversion to graft was 66.7%
  - findings: when using 2-point sutures, there were fewer cases where composite graft conversion was required
- Conclusion on minimization: results suggest that 2-point suturing is a feasible alternative to 3/4-point suturing in microvascular anastomosis, leading the authors to conclude that reducing the number of sutures aids in optimizing perfusion
- General complications of or requirements of suturing
  - suture material is a foreign body in the lumen, which could lead to thrombosis
  - stitching itself causes surgical trauma
  - suture material thickness: authors state that using thinner threads (Nylon 11-0 or smaller), outcomes of 3/4-point may have been improved

OTHER INFORMATION - Named Microvascular Suture Techniques

- 12-6 Method (Conventional) - first suture is placed at 12 o’clock (0 degrees), and the second is placed at 6 o’clock (180 degrees). It requires turning the vessel 180 degrees with a clamp to suture the posterior wall, which may cause blood vessel damage
- 3-9 Side-Side Method (Yu et al. 1986) - The first suture is placed on the posterior wall, and the second is placed at a 90-degree angle to the anterior wall. The 90-degree rotation (compared to 180 degrees) is intended to reduce potential damage to the endothelium

- Triangular Method (Alexis Carrel, 1902) - Involves three standard stitches made at an angle of 120 degrees, followed by two more stitches between each standard stitch. This technique can lift the lumen with two standard stitches, which helps reduce the chance of suturing the posterior wall together.
- Posterior Wall First Technique (Harris et al. 1981, or "Backup" Technique) - The first suture is placed in the center of the posterior wall. This method provides constant visualization of the back wall, reducing the risk of accidentally catching the back wall. It is generally concluded to be less complicated, faster, and easier to perform than the anterior wall technique.

Conclusions/action items:

In standard microsurgical anastomosis, the same limitations apply: sutures add bulk to the lumen, and higher stitch counts increase ischemia time. While vessels are smaller in supermicrosurgery, minimizing suture number and material thickness still improves flow and reduces trauma. In the future, it would be valuable to assess the optimal balance of stitch count vs. lumen preservation in regular microsurgery, and explore whether simplified suture techniques or sutureless coupler devices can replicate the benefits seen in reduced-suture approaches.

Source:

[1] H. Yi, B. Kim, Y. Kim, J. Park, and H. Kim, “What Is the Minimum Number of Sutures for Microvascular Anastomosis during Replantation?,” *J Clin Med*, vol. 12, no. 8, p. 2891, Apr. 2023, doi: 10.3390/jcm12082891.

2025/10/07 - Nitinol

Title: Nitinol Research

Date: 10/7/2025

Content by: Daniel Pies

Present: n/a

Goals: Take notes on Nitinol material for use in design 3

Content:

Nitinol Fundamentals

- Nitinol is a Shape Memory Alloy (SMA) composed of nickel and titanium. The acronym stands for Nickel Titanium–Naval Ordinance Laboratory.

Unique Material Properties

- Nitinol is attractive for fracture surgery due to two unique properties: pseudoelasticity and shape memory.
- Pseudoelasticity (Super-Elasticity):
  - Allows an elastic response caused by a phase transformation.
  - Nitinol can tolerate up to 8% strain before plastic deformation, making it 16 to 32 times more elastic than common orthopedic alloys (0.25% to 0.
- Shape Memory:
  - The ability to undergo reversible deformation based on temperature changes.
  - Martensite Phase: Exists below the transition temperature; exhibits extremely elastic/flexible properties.
  - Austenite Phase: Exists above the transition temperature; releases stored energy, returns to a stable conformation, and becomes rigid.

SMA Staple Mechanism

- Activation: Most SMA staple implants are manufactured with a transition temperature set just below body temperature.
- Insertion: The staple is cooled (Martensite phase), opened, and inserted into the bone.
- Compression: Ambient body temperature (warming) triggers the phase change to Austenite, causing the staple to return to its original, manufactured c
- Result: This mechanism generates continuous interfragmentary compression across the fracture site until the staple fully returns to its resting shape, c conventional static implants.

Conclusions/action items:

Nitinol is an established, safe, and effective material for endovasular use, specifically in stents, where its unique properties can be leveraged to create self-e

Leverage Shape Memory for Deployment: Utilize the shape memory effect to design a stent that is flexible and deformed in its cool, delivery state (Martensi manufactured in its final, open, rigid state. Upon warming by ambient body temperature, the stent will return to its rigid conformation (Austenite phase), ensu expansion within the vessel

Source:

[1] “Fracture Fixation Using Shape-Memory (Ninitol) Staples - ClinicalKey.” Accessed: Oct. 07, 2025. [Online]. Available: https://www.clinicalkey.com/?adobe_mc=MCMID%3D21082904837742235984535863003632819506%7CMCORGID%3D4D6368F454EC41940A4C98A6%2540AdobeOrg%7CTS%3D s2.0-S0030589819300033

Daniel Pies - Oct 07, 2025, 12:48 PM CDT

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nitinolpdf.pdf (1.22 MB)

2025/10/07 - PTFE

Daniel Pies - Dec 02, 2025, 2:04 PM CST

Title: PTFE Researchh

Date: 10/7/2025

Content by: Daniel Pies

Present: n/a

Goals: Take notes on the material PTFE for potential application in design 3's loading tube

Content:

Polymer Composite Materials (PCMs)

Low Friction Requirements

- PTFE has distinctive antifriction properties and a low friction coefficient
- the addition of fillers generally increases the friction coefficient
- the lowest friction coefficients among the composites studied were achieved using 1 wt % mechanically activated kaolinite (Kl) and 1–8 wt % carbon fiber (CF).

Strength and Wear Resistance

- Use of a mixed filler containing layered silicates (like Kl or vermiculite, Vl) and Carbon Fiber is necessary to overcome pure PTFE's low wear resistance and cold flow
- above combination leads to a 55% increase in yield strength and a 60% increase in compressive strength compared to the initial polymer matrix. The wear resistance improvement is highly significant, increasing by 850 times due to the formation of hard "tribofilms" on the surface, which protect the polymer from abrasion.

Flexibility Retention

- Addition of mixed fillers designed to enhance strength did not compromise flexibility, as the elongation-at-break values of the PCMs were similar to that of the initial PTFE over the entire concentration range

Conclusions/action items:

Given that mechanical properties of the loading tube rely heavily on achieving a suitable effect between the polymer and reinforcing agents, further research should be done on selecting the precise type and weight concentration of fillers required to manufacture the pcm.

Source:

[1] A. P. Vasilev et al., “Mechanical and Tribological Properties of Polytetrafluoroethylene Composites with Carbon Fiber and Layered Silicate Fillers,” Molecules, vol. 24, no. 2, p. 224, Jan. 2019, doi: 10.3390/molecules24020224.


molecules

Mechanical and Tribological Properties of Polytetrafluoroethylene Composites with Carbon Fiber and Layered Silicate Fillers

Download

ptfe.pdf (4.35 MB)

2025/10/16- ISO-25539-2-2020

Daniel Pies - Oct 16, 2025, 11:27 AM CDT

Title: ISO-25539-2-2020

Date: 10/16/2025

Content by: Daniel Pies

Present: n/a

Goals: Take notes on this standard as it applies to the testing and fabrication protocols that could be used on the anastomosis recoupler

Content:

General Device Requirements

- Our device is a "stent system", defined vascular stent and its delivery system
- standards apply to vascular stents (implants transluminally placed, balloon-expandable or self-expanding) intended to maintain or restore vessel patency or function

Stent Type and Configuration

- must designate the stent type as self-expanding. A self-expanding stent increases in diameter when released from the delivery mechanism without mechanical assistance (like balloon inflation).
- must designate the stent's configuration (shape and geometry), which could be cylindrical, articulated, closed cell, or open cell.

Size and Performance Designation

- For the self-expanding stent, the size designation must include:
    - The unconstrained outer diameter (in millimeters).
    - The intended vessel lumen diameter range (in millimeters).
    - The usable length (in millimeters or centimeters)
- We must designate the materials of construction (e.g., wire, coatings) by their generic or chemical names.

Intended Clinical Use

- The intended clinical use for the anastomosis device must be clearly designated:
    - Arterial, venous, or arterio-venous.
    - The specific disease state or lesion type to be treated (e.g., de novo stenosis, dissection, external compression).
    - The intended implant site (e.g., iliac, renal, popliteal, other arteries to be specified).

Device Evaluation Strategy (Protocol Foundation)

- The testing protocol should be established as a device evaluation strategy, which provides the rationale for the testing selected based on the device design requirements and potential failure modes. Guidance for developing this strategy is provided in Annex A.
- Failure Modes: The testing should address potential failure modes (difficulties or failures encountered during preclinical or clinical use that could cause harm).
    - Annex A provides the relationship between testing requirements, device attributes, and potential failure modes.
    - We can refer to Annex B for descriptions of potential clinical effects of failure.
    - We can refer to Annex C for descriptions of potential device effects of failure.
- Strategy Approach: We should determine if a focused device evaluation strategy table (focusing on unique characteristics or intended use aspects) or a comprehensive device evaluation strategy table (addressing all attributes and failure modes) is appropriate.

Analytical Tests
Design evaluation (Clause 8) requires bench and analytical tests. Guidance for developing appropriate test methods is found in Annex D.
Mechanical Durability and Fatigue

- We must include requirements for evaluating fatigue and durability.
- The revised standard emphasizes the addition of non-radial durability testing.

- If using computational analyses for fatigue and durability, the guidance requires recommendations regarding verification of the solution and validation of the computational model, as well as detailed reporting.
- Testing for radial fatigue and durability is included, with sample equations provided in Annex D.

Deployment and Delivery System Performance

- The evaluation of functional attributes related to the delivery process are now incorporated within a mandatory simulated use evaluation requirement.
- The simulated use testing must evaluate:
    - Flexibility
    - Torquability
    - Trackability
    - Deployment accuracy
- Guidance on the model development for simulated use has been revised to improve the clinical relevance of this testing.

Functional Performance

- Specific requirements for testing to evaluate patency-related characteristics have been added in the updated standard. This is crucial for an anastomosis device intended to maintain flow.
- The test results for quantitative parameters should generally be compared to a quantitative acceptance criteria. For characterization tests, an explanation of the relevance of the results must be provided.

Materials and Coatings (If Applicable)

- General Materials: Materials of construction shall be described.
- Absorbable/Drug Characteristics: Although our device is a bare metal Nitinol stent, if we add coatings or absorbable elements later, we note that the document addresses requirements for absorbable stents and absorbable coatings and drug-eluting stents (DES), though it is not comprehensive regarding those properties. Drug-eluting stents (DES) release a drug, while drug-containing stents have a coating that is not intended to release the drug.
- Biological Evaluation: Any materials used must undergo evaluation according to ISO 10993 (all parts), Biological evaluation of medical devices.

Conclusions/action items:

The testing protocol for the self-expanding Nitinol stent system must comprehensively address design, performance, durability, and biocompatibility to ensure safety and effectiveness for its intended vascular application. By aligning with ISO 25539-2 and related standards, the evaluation strategy will validate the device's ability to maintain vessel patency and function under clinically relevant conditions.

Source:

"ISO-25539-2-2020.pdf." Accessed: Oct. 16, 2025. [Online]. Available: https://cdn.standards.iteh.ai/samples/69835/ba91d121a7b94111b386298ae99ff327/ISO-25539-2-2020.pdf


INTERNATIONAL STANDARD

ISO 25539-2

Cardiovascular implants — Endovascular devices —

Part 2: Vascular stents

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2025/10/16 - Oversizing of self-expanding Nitinol vascular stents

Daniel Pies - Dec 02, 2025, 2:04 PM CST

Title: Oversizing of self-expanding nitinol vascular stents

Date: 10/16/2025

Content by: Daniel Pies

Present: n/a

Goals: Investigate source for potential on how to control expansion diameter of nitinol stents as per client's request

Content

Diameter Control through Pre-Selection (Oversizing Ratio, OS)

- controlling the effective diameter of the deployed self-expanding stent is through the deliberate oversizing ratio
- Oversizing Ratio (OS) - OS is defined as the ratio between the nominal stent diameter and the average vessel diameter.
    - The OS values analyzed in this study ranged from 1.0 to 1.8.

Optimal Diameter Control: The study's computational model found that oversizing ratios in the range $1.2 \leq OS \leq 1.4$ provided the optimum biomechanical performance following implantation.

- This range offered improved lumen gain (LG), reduced incomplete stent apposition (ISA), and favorable predicted long-term fatigue performance.

Limiting Expansion Through Optimal Sizing:

- Low Oversizing ($OS < 1.2$): Resulted in problematic short-term outcomes, including poor lumen gain and significant strut "malapposition"
- Excessive Oversizing ($OS > 1.4$): Did not provide further benefit in acute outcomes (marginal increase in LG and ISA reduction). Crucially, excessive oversizing led to unfavourable long-term performance, showing higher mean strain values predicted from the fatigue analysis. Excessive oversizing is also known clinically to cause undesired mechanical dilatation of the vessel wall and potentially an exaggerated healing response. This acts as a necessary limit on stent size selection.

2. Stent Expansion Mechanism and Constraint

- Self-expanding Nitinol stents, like the Zilver PTX modeled in the study, are designed to expand due to their superelasticity until they reach an equilibrium diameter constrained by the vessel wall
- Self-Expansion: Self-expanding Nitinol devices are the current gold standard because their superelasticity and flexible designs allow them to accommodate large external deformations
- Constraint: Oversizing is necessary to obtain suitable lumen gain and apposition to the vessel wall. The final effective diameter of the stent is determined by the interaction (contact and resulting stress) between the expanding stent and the arterial wall. The confinement exerted on the stent from the vessel is fundamental in determining its fatigue life

Conclusions/action items:

While this source does not provide any direct methods for "manually limiting stent diameter," it is important to consider these factors when selecting an initial stent diameter.

Source:

[1] M. Bernini et al., “Oversizing of self-expanding Nitinol vascular stents – A biomechanical investigation in the superficial femoral artery,” Journal of the Mechanical Behavior of Biomedical Materials, vol. 132, p. 105259, Aug. 2022, doi: 10.1016/j.jmbbm.2022.105259.

2025/10/29 - Clinical Impact of Stent Design

Daniel Pies - Dec 02, 2025, 2:05 PM CST

Title: Clinical Impact of Stent Design

Date: 10/29/2205

Content by: Daniel Pies

Present: n/a

Goals: Take notes on this review article to gather information on why certain stent properties, most importantly geometry, are selected, and what factors they influence/impact

Content:

Selection Rationale and Historical Evolution of Design:

- Bare metal stents (BMS) were developed to resolve limitations of plain old balloon angioplasty (POBA), specifically preventing abrupt vessel closure due to coronary dissection and subacute recoil
- Early BMS were relatively bulky and stiff, suitable for treating focal and straightforward coronary lesions
- The late complication of in-stent restenosis (ISR) associated with BMS drove the need for drug-eluting stents (DES)
- The therapeutic goal of DES was to reduce the inflammatory and healing response invoked by stent implantation to stop late lumen loss and prevent ISR
- Initially, manufacturers focused research primarily on different drugs, polymers, and their combinations, which essentially superseded platform design
- Stent platform design returned to the clinical spotlight due to the expanding use of devices in complex clinical areas
- Operator feedback pushed manufacturers to incorporate desirable properties, including improved radiographic visibility, flexibility, device deliverability, and conformity to the vessel
- The overall design trend has been to produce thinner stents that are more flexible while preserving the key mechanical property of radial strength

Impacts of Material and Strut Factors:

- Material Composition: Stents are constructed from various metallic alloys, including 316L stainless steel, cobalt chromium alloys (MP35N and L605), and platinum chromium alloys. Bioresorbable scaffolds are made from polymers like poly-L-lactic acid (PLLA)
- Radio-opacity: This is mainly dictated by the material, where resistance to X-ray penetration is proportional to the cube of the atomic number of the constituent elements
- Mechanical Properties: The alloy dictates the elastic modulus, yield strength, and tensile strength, which collectively dictate the overall radial strength and susceptibility to recoil
- Strut Thinning: The evolution away from stainless steel toward newer alloys (like cobalt and platinum chromium) was necessary to allow struts to become thinner while maintaining overall radial strength
- Metal:Artery Ratio and Strut Thickness
    - A high metal:artery ratio and thick struts were design features of BMS that contributed to the late complication of ISR

Impacts of Geometry and Connectors (Longitudinal Stability vs. Flexibility):

- Geometry Determination: Stent geometry is determined by the number and pattern of connectors between rings or hoops. Stent construction varies (open versus closed cell)
- Fewer Connectors: Reducing the number of fixed connectors improves flexibility, enhances delivery, and decreases the metal:artery ratio. However, this potentially impacts longitudinal strength negatively
- More Connectors/Longitudinal Alignment (Stiffness): More connectors between rings correlate with increasing longitudinal strength. Connectors in longitudinal alignment confer increasing strength. However, this increased strength results in greater 'stiffness,' reducing the stent's deliverability and conformability within the vessel
- Longitudinal Stent Deformation (LSD):
    - LSD (or concertina effect) occurs when longer, thinner, and more flexible stents are compressed along their length

    - LSD is usually related to interaction between guiding catheters and stents deployed in the aorto-ostial position, or secondary equipment catching and distorting relatively undersized stents
    - The longitudinal strength of the platform is dictated by the construction of the device, the number of connectors, and their geometrical distribution. Stent alloy and strut thickness appear somewhat less important regarding susceptibility to LSD
    - Unrecognized LSD has the potential to be clinically disastrous, although it appears relatively rare

Impacts of Stiffness and Stent Fracture:

- Increased Risk: The risk of stent fracture increases as the stent becomes stiffer
- Observed Incidence: Older, stiffer platforms (like the 6-connector Cypher stent) were over four times more likely to fracture than newer platforms. Fracture has also been reported in thinner strut, 3-connector stents
- Predisposing Features: Features predisposing to stent fracture include treating the right coronary artery, using longer stents, areas of tortuosity, calcification, stent malapposition, and stenting at hinge points
- Clinical Consequence: Stent fracture is likely to lead to ISR, acute or chronic occlusion, is not a benign phenomenon, and carries a high chance of an adverse outcome

Impacts of Expansion and Apposition:

- Underexpansion/Malapposition: Underexpansion or incomplete stent apposition of BMS or DES is strongly associated with ISR and stent thrombosis and must be avoided
- Over-expansion Rationale (LMS): Over-expansion is frequently required in Left Main Stem (LMS) intervention to achieve apposition to the non-diseased vessel wall, as devices are brought back from smaller daughter vessels
- Theoretical Concerns of Over-expansion: Theoretical concerns include damage to the stent polymer (leading to uneven drug elution and potential later ISR), mechanical disruption/stent fracture, and potential stent recoil due to a reduction in metal:artery ratio
- Observed Impact of Over-expansion: Bench testing shows current DES platforms maintain structural integrity beyond the nominal expansion diameter. Paradoxically, the radial strength of the stent increases as it is over-expanded because the rings and connectors straighten, leading to greater strength
- Clinical Efficacy of Over-expansion: Clinical studies show excellent short-term efficacy and no increased complication rate when current generation DES are post-dilated beyond suggested expansion limits in the LMS

Source:

[1] R. L. Noad, C. G. Hanratty, and S. J. Walsh, “Clinical Impact of Stent Design,” Interv Cardiol, vol. 9, no. 2, pp. 89–93, Apr. 2014, doi: 10.15420/icr.2011.9.2.89.

Download

clinical_impact_of_stent_design.pdf (818 kB)

2025/11/24 - Clinical/Physiological Source for Hemodynamic Modeling

Daniel Pies - Dec 02, 2025, 2:05 PM CST

Title: Source for Clinical/Physiological Source for Hemodynamic Modeling

Date: 11/24/2025

Content by: Daniel Pies

Present: n/a

Goals: understand modeling flow/perfusion in small arteries

Content:

small muscular arteries are downstream and see lower pressure and flow in PAD vs healthy, see altered perfusion patterns

this justifies comparing normal vs reduced flow cases?

consider pressure drops across a lesion and their impact on distal small-artery flow?

Normal: small arteries can increase flow substantially with demand (higher velocity/flow boundary conditions)

PAD: lower baseline flow, smaller/delayed increase in flow during simulated "exercise"

Conclusions/action items:

This source was not particularly useful in determining flow rates/perfusions for flow modeling.

Source:

[1] B. A. Venkatesh et al., “Baseline Assessment and Comparison of Arterial Anatomy, Hyperemic Flow and Skeletal Muscle Perfusion in Peripheral Artery Disease: The CCTRN PACE Study,” Am Heart J, vol. 183, pp. 24–34, Jan. 2017, doi: 10.1016/j.ahj.2016.09.013.

2025/11/25 - Blood Flow, Blood Pressure, Resistance

Daniel Pies - Dec 02, 2025, 1:57 PM CST

Title: Blood Flow, Blood Pressure, Resistance

Date: 11/25/2025

Content by: Daniel Pies

Present: n/a

Goals: Take notes on literature source for SolidWorks simulation, to know what literature values to use for flow simulation

Content:

Systemic arteries are driven by arterial blood pressure: systolic ~120mmHg, diastolic ~80mmHg, MAP ~90-100mmHg
MAP is single best value for "average driving pressure" over cardiac cycle

Assumption: Transmural pressure ~100mmHg, physiologically reasonable for small/medium muscular artery at rest, matches typical MAP used in hemodynamic analyses

"Small Artery" - lumen diameter on order of a few millimeters (not arterioles)

using D=3mm

r=1.5mm, A=pi*r^2 -> ~7.70x10^-6 m^2

Velocity to volumetric flow:

Q=v*A, v=.2m/s, A = 7.70x10^-6 m^2, Q=1.41x10^-6 m^3/s = (conversion) = 1.41mL/s * 60 = 84.6mL/min

Mass Flow Rate from Volumetric Flow:

MFR=rho*Q
blood density ~1060kg/m^3

Q=above
corresponding mass flow ~0.0015kg/s

Pressure: Using ≈100 mmHg aligns with mean arterial pressure ranges described (MAP 70–110 mmHg), which represent the effective “driving” pressure for systemic arteries at rest.

Conclusions/action items:

For use in solidworks flow simulation -> Inlet can be set as either a mean velocity of 0.2 m/s or a mass flow of 0.0015 kg/s, while outlet can be set using a pressure reference consistent with ≈100 mmHg transmural pressure (or a pressure drop chosen for the segment).

Source:

[1] “Blood Flow, Blood Pressure, and Resistance | Anatomy and Physiology II.” Accessed: Dec. 02, 2025. [Online]. Available: https://courses.lumenlearning.com/suny-ap2/chapter/blood-flow-blood-pressure-and-resistance-no-content/

2025/12/02 - Material property estimation for tubes and arteries using ultrasound radiation force and analysis of propagating modes

Daniel Pies - Dec 02, 2025, 2:07 PM CST

Title: Determining Hoop Stresses for Small-Medium Artery and Nitinol Stent

Date: 12/2/2025

Content by: Daniel Pies

Present: n/a

Goals: Use this literature source to find and/or calculate expected hoop stress of a small artery and a nitinol stent

Content:

for thin-walled cylinder hoop stress

$\sigma_\theta = \frac{p\,d}{2t}$ where p is internal pressure, d inner diameter, t wall thickness.

Artery:

- 0.5mm wall thickness

- 3mm inner diameter

- p = transmural pressure = 100mmHg = ~0.01333 MPa

so hoop stress Sigma=~40kPa
OR a reasonable range of ~20kPa to 100kPa depending on the patient and conditions

Nitinol:

- 0.11mm wall thickness

- 3.0mm inner diameter

- p = transmural pressure = 100mmHg = ~0.01333 MPa

so hoop stress Sigma= ~182kPa

nitinol modulus ~50-80GPa, gives tiny strain at this stress

If we had a full stack, artery->stent->artery->artery

Layer (inside → outside)	Given / derived geometry	Inner diameter d (mm)	Wall t (mm)	Hoop stress σ_θ at 100 mmHg
Inner artery	$OD = 3.0\ \text{mm}, t = 0.5\ \text{mm}$	2.0	0.5	$\approx 0.0267\ \text{MPa} = 26.7\ \text{kPa}$
Nitinol stent	$ID = 3.0\ \text{mm}, t = 0.11\ \text{mm}$	3.0	0.11	$\approx 0.182\ \text{MPa} = 182\ \text{kPa}$
Middle artery	Inner on stent OD, $t = 0.5\ \text{mm}$	3.22	0.5	$\approx 0.0429\ \text{MPa} = 42.9\ \text{kPa}$
Outer artery	Inner on middle OD, $t = 0.5\ \text{mm}$	4.22	0.5	$\approx 0.0563\ \text{MPa} = 56.3\ \text{kPa}$

Conclusions/action items:

Refer to these calculations for references ranges of SolidWorks modeling

Sources:

[1] D. Stoeckel, A. Pelton, and T. Duerig, “Self-expanding nitinol stents: material and design considerations,” Eur Radiol, vol. 14, no. 2, pp. 292–301, Feb. 2004, doi: 10.1007/s00330-003-2022-5.

[2] I. Masson, P. Boutouyrie, S. Laurent, J. D. Humphrey, and M. Zidi, “Characterization of arterial wall mechanical behavior and stresses from human clinical data,” J Biomech, vol. 41, no. 12, pp. 2618–2627, Aug. 2008, doi: 10.1016/j.jbiomech.2008.06.022.

2025/12/02- Computational Modeling of Blood Flow in Arterial Stenoses

Daniel Pies - Dec 08, 2025, 12:48 PM CST

Title: Computational Modeling of Blood Flow in Arterial Stresses

Date: 12/2/2025

Content by: Daniel Pies

Present: n/a

Goals: Understand modeling techniques and validation strategies for simulating blood flow in small arteries (stenosed?), to refine SolidWorks inputs (e.g. boundary conditions, mesh, etc.) for realistic scenarios

Content:

Non-newtonian blood rheology (casson model?) - pulsatile inlet, rigid/compliant walls

For ~3mm diameter arteries

Inlet: Use time-varying velocity (e.g., peak ~0.5–1 m/s systolic, mean 0.2 m/s) based on cardiac cycle; outlet pressure ~80-100 mmHg diastolic reference.

(OPTIONAL) Stenosis effects: Flow separation creates low-shear zones (stagnation), reducing effective perfusion; model with 50-70% area reduction for PAD.

Output: Wall shear stress (WSS) maps show endothelial damage risk; perfusion drops ~30-50% distal to severe stenosis.

Practical Tips

Mesh: use finer walls/stenosis (y+< 5 for turbulence models); validate against Poiseuille for healthy segments

Validation: compare simulated pressure drop and velocity profiles to in vivo Doppler data

Perfusion: post-stenosis turbulence impairs nutrients delivery, so justify heterogenous flow in muscle beds.

Conclusions/action items:

This information and tips can be applied in future Solidworks modeling/testing, and team can ensure accuracy via finer meshing and validation against well-recognized Poiseuille and Doppler data.

Source:

[1] J. S. Bell et al., “Microstructure and mechanics of human resistance arteries,” Am J Physiol Heart Circ Physiol, vol. 311, no. 6, pp. H1560–H1568, Dec. 2016, doi: 10.1152/ajpheart.00002.2016.

2025/09/16 - Synovis Device

Daniel Pies - Sep 16, 2025, 8:29 PM CDT

Title: Synovis Microvascular Anastomotic Coupler - Competing Design

Date: 9/16/2025

Content by: Daniel

Present: n/a

Goals: Document competing design, to use for inspiration, but to also avoid IP infringement

Content:

The microvascular anastomotic coupler by Synovis, pictured below, is the forefront of coupling technology for anastomosis procedures.

- Specifically designed for use in the anastomosis of veins and arteries

- intended for use with veins and arteries having an outside diameter no smaller than 0.8mm and no larger than 4.3mm, and a wall thickness of 0.5mm or less.

Contraindications:
The coupler device is not indicated for use in patients presenting conditions that would normally preclude microvascular repair with suture technique. Examples of such conditions include, but are not limited to:

- Pre-existing or suspected peripheral vascular disease
- Ongoing irradiation of the area of reconstruction
- Clinical infection of the area of reconstruction
- Anticipated infection due to significant contamination of the area of reconstruction
- Friability of the vascular tissue due to sclerotic conditions
- Concurrent diabetes mellitus
- Concurrent corticosteroid therapy

Conclusions/action items:

This device is the same as the client initially showed the team, verifying the idea that this device is the forefront of technology. Further investigation can be done to identify weaknesses in this design so that they may be avoided in the design processes.

Source:

[1] “Microvascular Anastomotic Coupler | Microvascular Anastomosis Couplers.” Accessed: Sept. 16, 2025. [Online]. Available: https://www.synovismicro.com/html/products/gem_microvascular_anastomotic_coupler.html?

2025/09/24 - US10842493B2 Competing Device

Daniel Pies - Sep 24, 2025, 12:31 PM CDT

Title: Patent No. US10842493B2 - Competing Device

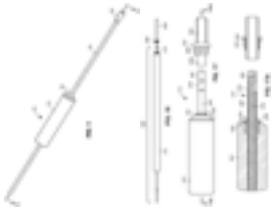
Date: 9/24/2025

Content by: Daniel Pies

Present: n/a

Goals: Take notes on this competing device to avoid IP infringement and also gain inspiration

Content:



The device described in in US10842493B2 is an eversion device designed to address the difficulties in securing artery segments to other existing micro-anastomotic coupling devices. This device supports the vessel wall during anastomosis procedures so the vessel doesn't buckle or slip off the coupler's pins. Support can come from either a balloon or plunger, or expansion of the shaft inside the artery.

The tip features a contoured surface that folds the vessel end over the coupler's ring, which lets the ring's pins pierce through. Slots in the tip align with the pins of the other device that guide them through the everted arterial tissue.

This device is designed specifically for arterial work, not venous.

Conclusions/action items:

This patent describes an instrument plus ring/pin coupler modification targeted at arterial tissue handling and coupler implantation. This device should be notes for future reference to be sure no patented technology is directly included in the team's design.

Source:

[1] J. S. Plott *et al.*, “Device to aid in arterial microvascular anastomosis,” US10842493B2, Nov. 24, 2020 Accessed: Sept. 24, 2025. [Online]. Available: https://patents.google.com/patent/US10842493B2/en

2025/09/24 - US20240268829A1 Anastomotic Coupler

Daniel Pies - Sep 24, 2025, 12:44 PM CDT

Title: Competing Design - Anastomotic coupler US20240268829A1

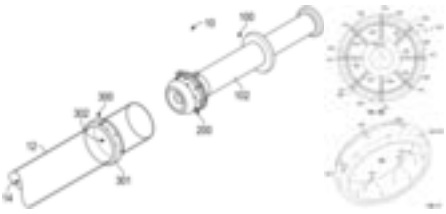
Date: 9/24/2025

Content by: Daniel Pies

Present: n/a

Goals: Document competing design for reference and avoiding IP infringement

Content:



This is an anastomotic coupler device by Donald W Buck. This coupler system features a ring with "receiving slots" paired with cartridge holding fasteners. When actuated, the fasteners pierce through the vessel's wall, locking into the ring's receiving portion, securing the vessel to the ring.

The device described in US20240268829A1 is intended to create a reliable, sealed connection between two tubular structures (not specifically arterial, but also vesicular?), including blood vessels, GI structures, or lymphatics. This technology aimed to overcome the drawbacks associated with the convention method of manual suturing or other coupler designs.

How does this device overcome competition?

- This device uses radially driven fasteners

- the fixation device inserts a cartridge into the vessel's lumen and drives fasteners (such as tacks or staples) radially outward, through the vessel wall, and into receiving portions of an external ring, securing the tissue without requiring the complex technique of everting the vessel over pins

- Goal of Device - more reliable, faster, and more secure, creating sealed, leak-proof, open connection between tubular structure, providing "stented" unobstructed flow of content of vessel contents. One notable strength is the ability to withstand high flow pressure, tension, and traction

The device uses a male ring and female ring to mate tubular structures, for lumen diameters between .5mm and 60mm (for GI connection).

Conclusions/action items:

See link for cleared images and depiction of device. This device is particularly interesting, and although it uses components that directly contact the lumen, which the client for this project did not want, provides a good idea and basis for potential mating mechanisms, specifically being radially driven fasteners. This patent could be a good basis for developing the anastomosis device.

Source:

[1] D. W. Buck, “Anastomotic coupler,” US20240268829A1, Aug. 15, 2024 Accessed: Sept. 24, 2025. [Online]. Available: https://patents.google.com/patent/US20240268829A1/en

2025/09/22 - Collet Grip

Daniel Pies - Sep 23, 2025, 10:43 AM CDT

Title: Preliminary Design - Collet Grip

Date: 9/22/25

Content by: Daniel Pies

Present: n/a

Goals: Document preliminary design

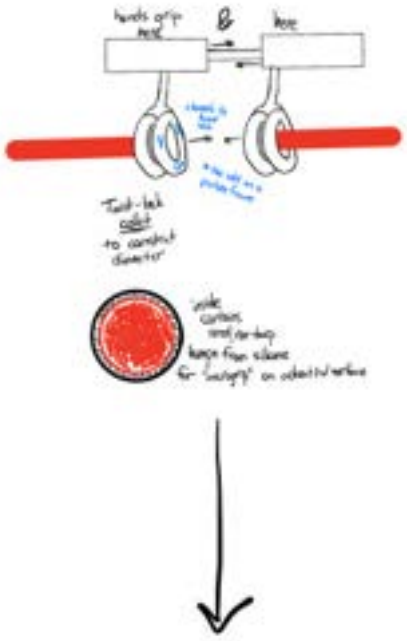
Content:

See attached PDF below

Conclusions/action items:

This design can be evaluated via design matrix for comparison against other designs/ideas.

Daniel Pies - Sep 23, 2025, 10:43 AM CDT



Download

Preliminary_designs.pdf (663 kB)

2025/10/17 - UW Human Subjects Protections Course

Daniel Pies - Oct 17, 2025, 1:12 PM CDT

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danielpiescitiCompletionCertificate_14428766_69423205.pdf (77.4 kB)

2025/10/17 - Good Clinical Practice for Drug/Device Researchers

Daniel Pies - Oct 17, 2025, 1:13 PM CDT

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2025/10/17 - Safety Trainings

Daniel Pies - Oct 17, 2025, 1:17 PM CDT

Download

danielpiessafetytrainings.png (128 kB)

2025/09/10-Video example of micro-anastomosis, hand tie

JACKIE BEHRING - Sep 10, 2025, 11:28 AM CDT

Title: Video example of micro-anastomosis, hand tie

Date: 09/10/2025

Content by: Jackie

Present: N/A

Goals: Watch video showing anastomosis of vein performed by Dr. Weifeng Zeng to understand procedure.

Content:

- Procedure was performed on a 2mm vein
- ETE: end-to-end
- Video title: 2mm vein ETE two-stay method
  - ETE: end-to-end
  - microvascular surgical technique to rejoin two severed ends of a blood vessel (vein in this case)
- Emphasis on precise needle handling
  - needle is **finest tool** for the entry space
  - critical for small vessels
  - guides itself into the right plane of tissue
- Open loop method prevents the anastomotic space from narrowing
- Front wall suturing
  - continuous open loop can be performed but requires high skill
  - option to tie and cut after each stitch
  - option to leave loops, cut later, then tie knots
- Back wall suturing - open loop method can be used for the last two stitches
- "Tent" technique - last stitch entry
  - one arm of forceps to life vessel wall edge - side of a tent
  - creates target for the needle bite when counter pressure is difficult
- Last stitch needle as splint - leaving needle in place can help evert (turn outward) the vessel edge to improve alignment
- Airborne technique - recommended approach

Questions:

- What are advantages/disadvantages of tying each knot immediately versus cutting loops later?
- Explanation/demonstration on the airborne technique.
- What are the most common sources of failure during these procedures?
- Do surgeons prefer a certain technique or is it based on personal or training preference?

URL: https://www.youtube.com/watch?v=yMw9DOjV9n4

Conclusions/action items: Use some of these questions for continued research or client meetings.

2025/09/10 - Project Description Breakdown

JACKIE BEHRING - Sep 10, 2025, 12:08 PM CDT

Title: Project Description Breakdown

Date: 09/10/2025

Content by: Jackie

Present: N/A

Goals: Breakdown project description and goals to create questions for client and team.

Content:

Microsurgical arterial anastomosis **(surgical connection between two tubular structures, such as blood vessels, organs, or intestine)** is a critical step in reconstructive, transplant, and trauma surgery, where the restoration of uninterrupted blood flow determines tissue viability and surgical success. Traditionally, arterial anastomoses are performed using hand-sewn microsutures **(extremely fine sutures, typically smaller than 6-0, used in delicate procedures)** under an operating microscope. While the gold standard for decades, this technique is technically demanding, time-intensive, and associated with a steep learning curve. Even in experienced hands, prolonged clamp time can increase ischemia risk **(inadequate blood flow to specific area of body)**, and suture-related trauma to the vessel wall can contribute to thrombosis **(blood clots block veins or arteries)**, intimal hyperplasia **(abnormal thickening of tunica intima, inner most layer of blood vessel, caused by overproduction of cells and ECM in response to injury)**, or anastomotic failure **(leakage of intestinal contents from a surgical connection, anastomosis, b/t two hollow organs)**.

Existing mechanical coupling devices have simplified venous anastomoses in some settings, but their application to arterial vessels is limited. Arteries differ from veins in their thicker, more elastic walls, higher intraluminal pressures, and greater tendency for spasm. These anatomical and physiological differences present unique challenges for mechanical connection—requiring secure, hemostatic, and atraumatic **(minimize tissue damage)** fixation while maintaining luminal patency and minimizing turbulence.

A novel arterial coupling solution has the potential to:

- Reduce operative time and ischemia **(inadequate blood flow)** duration.
- Decrease reliance on advanced microsurgical skill for primary vessel connection.
- Improve reproducibility and consistency of outcomes across surgical teams.
- Minimize vessel wall manipulation, thereby reducing the risk of thrombosis.
- Expand access to high-quality microsurgical care in settings with limited subspecialty expertise.

Recent advances in biomaterials, microfabrication, and device engineering—combined with improved understanding of hemodynamics—offer a unique opportunity to design an arterial coupling system specifically tailored to the mechanical and physiological demands of arterial repair.

This project seeks to bridge the gap between current hand-sewn microsurgical standards and the need for a faster, safer, and more accessible method of arterial anastomosis. While there are many ways to design this sort of device, one idea that could work is designing “cuff anastomosis” that has an expandable external stent which combines a method currently used in animal studies with stent technology that exists for endovascular approaches.

Conclusions/action items: Research current "cuff anastomosis" used in animal studies.

2025/09/12 - Microvascular Anastamotic Arterial Coupling; A Systematic Review

JACKIE BEHRING - Dec 08, 2025, 8:04 PM CST

Title: Microvascular Anastomotic Arterial Coupling: A Systemic Review

Date: 09/12/2025

Content by: Jackie

Present: N/a

Goals: Understand clinical performance, limitations, and surgeon-reported barriers of existing arterial coupling devices to inform design decisions for our adjustable stent/cuff

Content:

Overview

- Systematic review of arterial microvascular coupling devices
- PRISMA-guided search across 4 databases (Nov 2020)
- Included 20 studies out of 7,690 screened
- Total: 1,639 patients; 670 arterial anastomoses; 1,124 venous (context only)

Clinical Application

- Arterial couplers used mostly in:
    - Head and neck reconstruction (351 cases)
    - Breast (117)
    - Small number in upper/lower extremity
- Arterial use far less common than venous coupling
- Main hesitation: arterial wall properties
    - Thicker walls
    - Reduced pliability
    - Calcification
    - Diameter mismatch and geometry variability

Statistics

- Total arterial coupler success rate: 92.1% (617/670)
- Intra- or postoperative failures/troubleshooting: 8%
- Most failures associated with extremity reconstructions

Reasons for Failure

- Inadequate vessel pliability for eversion
- Difficulty aligning thicker arterial walls on rigid coupler rings
- Coupler ring bulk interfering with tight surgical fields
- Intimal damage risk during eversion
- Mismatch between arterial diameters

- Device size limitations restricting use in smaller or diseased arteries

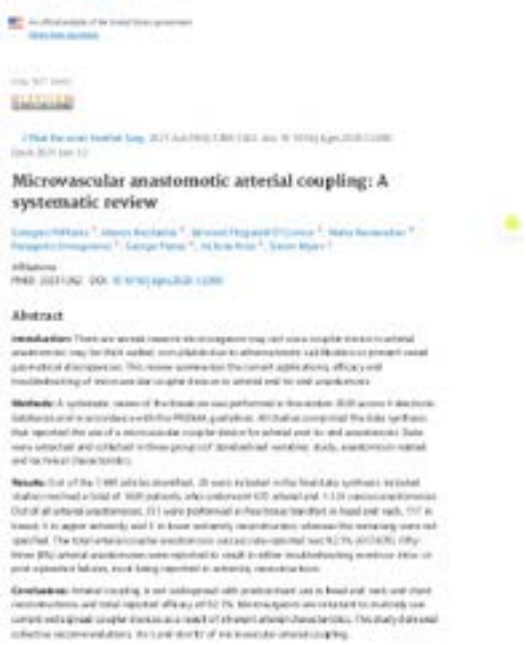
Relevance to Device Design

- Importance of minimal bulk at the coupling interface
- Need for a design that accommodates arterial stiffness
- Value of adjustable diameter systems for geometric variability
- Reduced need for forced vessel eversion could improve success rate
- Surgeons prefer intuitive, low-resistance vessel loading
- High success rates indicate viability if mechanical challenges addressed

URL: https://pubmed.ncbi.nlm.nih.gov/33551362/

Conclusions/action items: Design should explicitly address the key failure causes identified in the review (arterial stiffness, diameter mismatch, bulkiness), using them as constraints for geometry refinement

JACKIE BEHRING - Dec 08, 2025, 8:05 PM CST



Microvascular anastomotic arterial coupling: A systematic review

Abstract

Download

Microvascular_anastomotic_arterial_coupling__A_systematic_review_-_PubMed.pdf (118 kB)

2025/09/17- Cardiovascular Fluid Dynamics: A Journey Through our Circulation

JACKIE BEHRING - Dec 08, 2025, 8:27 PM CST

Title: Cardiovascular fluid Dynamics: a journey through our circulation

Date: 09/17/2025

Content by: Jackie

Present: N/a

Goals: Understand fluid-mechanics principles that directly affect vascular device performance (shear stress, flow patterns, vessel geometry).

Content:

Overview

- Review of fluid mechanics governing the cardiovascular system
- Heart as pulsatile pump driving flow through multiscale vessel network
- Blood vessels span ~100,000 km in adult circulation

Fluid Dynamics Concepts

- Reynolds numbers vary widely from aorta to capillaries (multiscale system)
- Womersley numbers change with pulsatile flow frequency
- Blood transitions from Newtonian-like behavior in large vessels to non-continuum behavior in microcirculation

Disease Relevance

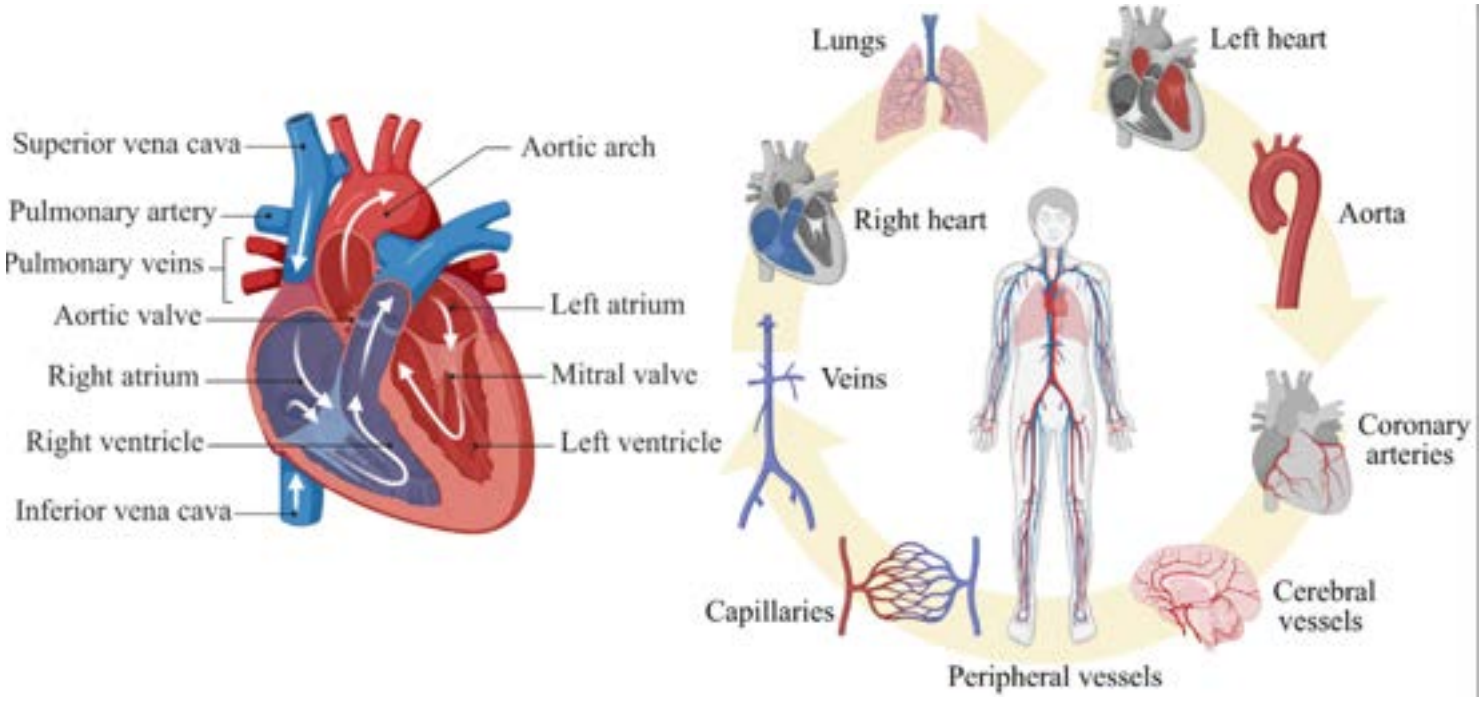
- Low and oscillatory shear stress strongly linked to atherosclerosis locations
- Complex flow patterns (helical flow, vortices, jets) influence thrombosis, aneurysm progression, valve performance
- Flow-induced forces impact endothelial mechanobiology and long-term disease progression

Computational Modeling

- Growth of image-based CFD using patient-specific anatomy
- CFD used to evaluate stenosis, aneurysms, dissections, coronary disease
- Haemodynamic metrics (pressure, flow) often better predictors of disease outcomes than geometry alone

Clinical Importance

- Haemodynamics increasingly used to guide treatment decisions
- Examples include fractional flow reserve (FFR), surgical planning, stent design



URL: https://www.cambridge.org/core/journals/flow/article/cardiovascular-fluid-dynamics-a-journey-through-our-circulation/9F5A4AC47AF2078276687C26E5668423

Conclusions/action items: Use cardiovascular shear-stress ranges and flow-regime data to define realistic anastomotic testing conditions, and incorporate CFD-based haemodynamic insights to guide pressure, flow, and shear benchmarks for evaluating the coupler design.

JACKIE BEHRING - Dec 08, 2025, 8:14 PM CST

Download

Cardiovascular_fluid_dynamics__a_journey_through_our_circulation___Flow___Cambridge_Core.pdf (4.32 MB)

2025/09/10 - Cuff Anastomosis of Renal Artery in Mice

JACKIE BEHRING - Sep 10, 2025, 12:49 PM CDT

Title: Cuff Anastomosis of Both Renal Artery and Vein to Minimize Thrombosis: A Novel Method of Kidney Transplantation in Mice

Date: 09/10/2025

Content by: Jackie

Present: N/A

Goals: Research cuff anastomosis to determine the limitations and strengths of design. Determine why this is not used in humans.

Content:

- Renal artery/vein anastomosis in mice is difficult with sutures
    - risk of thrombosis (blood clots blocking veins/arteries)
- Goal: develop cuff method for both artery and vein to simplify and reduce complications
- Method:
    - used BALB/c mice (donor and recipient)
    - artery cuff: seamless polyimide tubing (0.3 mm ID, 1 mm length)
    - vein cuff: inner tube of a 24G IV catheter
    - Technique:
        - transect vessel > pass through cuff > evert over cuff > secure with 8-0 silk
        - Insert cuffed vessel into donor vessel > tie with 8-0 suture
    - Isograft kidney transplantation performed (n=20)
- Results
    - total surgery time: ~77 min (artery ~7 min, vein ~7min)
    - 18/20 mice survived 12 weeks
    - stable renal function - serum creatine unchanged
    - no vascular thrombosis, stenosis, or chronic lesions (fibrosis, sclerosis)
- cuff method avoids suture related trauma > lower risk of thrombosis
- cuffs act like stents which prevent narrowing
- simpler than microsuture technique > less ischemia time
- limitation: not feasible in anatomical variants (double arteries)
- promising as a reliable model from renal transplantation in mice
- Cuff anastomosis of artery and vein is safe, effective, and minimizes thrombosis in mouse kidney transplant model

Comparison to humans

- Mice
    - arteries/veins ~0.3 mm
    - suturing extremely demanding
- Humans
    - larger arteries 2-6 mm
- Cuff / stent like devices reduce ischemia time, skill reliance, and risk of thrombosis

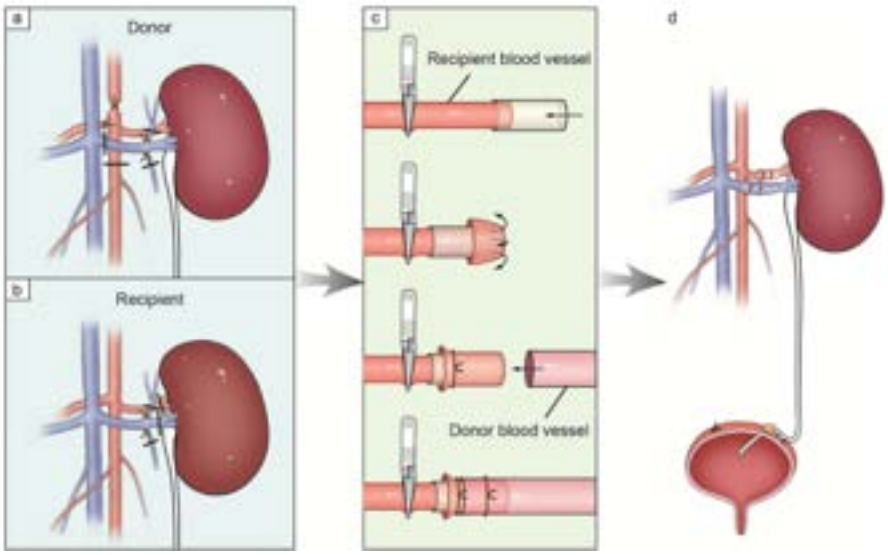


Figure 1: Diagram of the transplantation procedure.

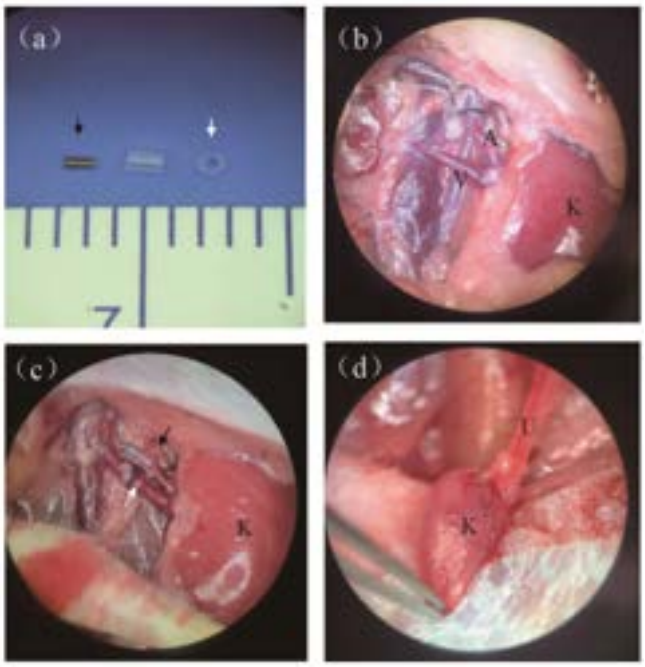


Figure 2: Photos of cuff technique in action.

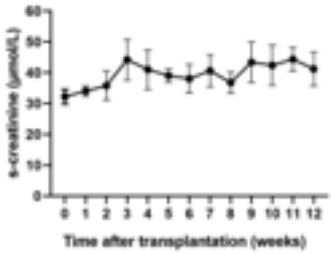


Figure 3: Graph showing serum creatine stability over 12 weeks.

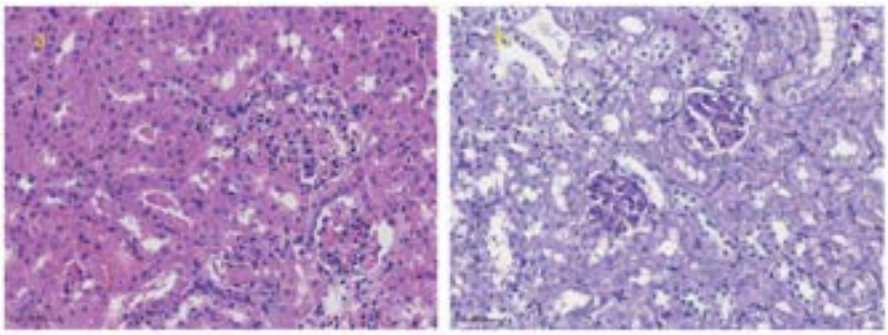


Figure 4: Histology images, H&E and PAS, confirming no thrombosis or chronic injury

URL: https://doi.org/10.1080/08941939.2020.1821264

Conclusions/action items: Use this information in future research and client questions.

JACKIE BEHRING - Sep 10, 2025, 12:48 PM CDT

Download

Cuff_Anastomosis_of_Both_Renal_Artery_and_Vein_to_Minimize_Thrombosis_A_Novel_Method_of_Kidney_Transplantation_in_Mice.pdf (1.68 MB)

2025/09/12 - A Novel Vascular Anastomotic Coupling Device for End-to-End Anastomosis of Arteries and VeinsHemodynamics & Vessel Wall Biology

JACKIE BEHRING - Dec 08, 2025, 7:54 PM CST

Title: A Novel Vascular Anastomotic Coupling Device for End-to-End Anastomosis of Arteries and Veins

Date: 09/12/2025

Content by: Jackie

Present: N/a

Goals: Understand how other small-diameter anastomotic devices achieve secure, fast, and leak-resistant vessel coupling so we can compare their performance benchmarks to our adjustable stent/cuff design.

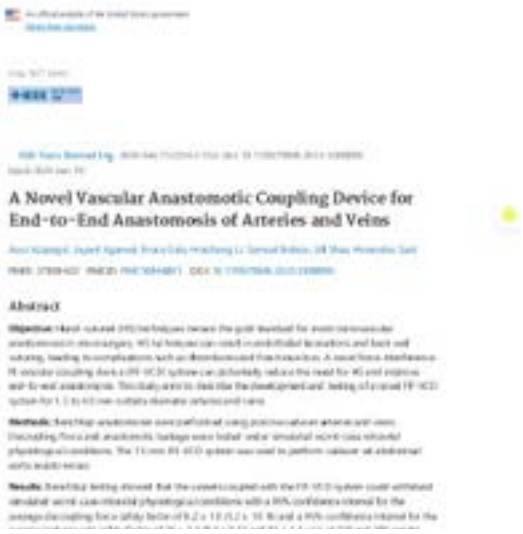
Content:

- Novel device: force-interference-fit vascular coupling device (FIF-VCD)
- Target vessels: 1.5–4.0 mm OD
- Decoupling force: ~5 N average (safety factor ~8.2)
- Leakage rates significantly lower than sutures at both pressures
- Leakage at 150 mmHg: FIF-VCD ~8.4 µL/s vs sutures ~310 µL/s
- Leakage at 360 mmHg: FIF-VCD ~95 µL/s vs sutures ~2100 µL/s
- Withstood simulated worst-case physiological pressures
- Successful installation in rat model (non-living)
- Motivation: hand suturing slow, high skill requirement, risk of endothelial injury
- FIF-VCD intended to reduce suturing, shorten operative time, improve consistency
- Tested on porcine cadaver vessels + rat abdominal aorta (feasibility)

URL: https://pubmed.ncbi.nlm.nih.gov/37639422/

Conclusions/action items: Use FIF-VCD performance metrics (retention force, leak rate, high-pressure tolerance) as benchmarks when defining the testing criteria for our own device.

JACKIE BEHRING - Dec 08, 2025, 7:54 PM CST



A Novel Vascular Anastomotic Coupling Device for End-to-End Anastomosis of Arteries and Veins

Abstract

Download

A_Novel_Vascular_Anastomotic_Coupling_Device_for_End-to-End_Anastomosis_of_Arteries_and_Veins_-_PubMed.pdf (233 kB)

2025/09/19 - A Novel Sutureless Anastomotic Device in a Swine Model: A Proof of Concept Study

JACKIE BEHRING - Dec 08, 2025, 8:39 PM CST

Title: A Novel Sutureless Anastomotic Device in a Swine Model

Date: 09/19/2025

Content by: Jackie

Present: N/a

Goals: Understand how a clinically tested sutureless anastomosis device performs in vivo, focusing on patency, healing, complication patterns, and device–artery interactions.

Content:

Overview

- Device: Vaso-Lock, a fully sutureless intraluminal implant for arterial/venous anastomosis
- Tested in pig arteriovenous loop (AVL) model
- Designed to eliminate hand sewing and standard coupler limitations

Study Design

- 18 pigs total
- Arteries and veins joined using Vaso-Lock
- Evaluation at multiple time points: early and late healing
- Measurements: flow, patency, thrombosis, tissue response, device stability

Key Findings

- Successful creation of AV loops using the sutureless device
- High patency rates reported at follow-up
- Minimal device migration
- Evidence of tissue ingrowth around the device
- Endothelialization observed at anastomotic interface
- Some cases of thrombosis or stenosis documented, generally linked to surgical technique rather than device failure

Device Mechanism

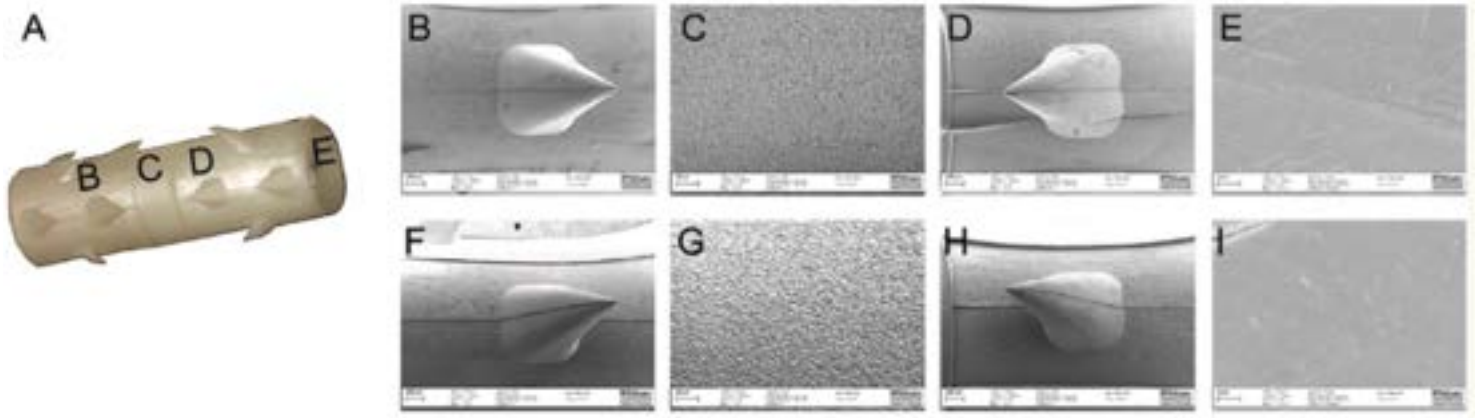
- Intraluminal anchor system
- Holds vessel ends in approximation without everted edges
- Reduces operative time
- Avoids problems of ring-based couplers (bulkiness, eversion difficulty)

Advantages vs. Suturing

- Faster procedure
- More consistent anastomosis geometry
- Potential reduction in variability among surgeons

Challenges

- Thrombosis risk still present
- Requires precise alignment during placement
- Long-term remodeling requires further study



URL: https://www.sciencedirect.com/science/article/pii/S0022480423001737
https://pmc.ncbi.nlm.nih.gov/articles/PMC11453428/

Conclusions/action items: Incorporate Vaso-Lock findings into our design criteria by prioritizing rapid implantation, secure intraluminal fixation, and minimization of thrombosis through smooth surfaces and controlled interface geometry.

2025/09/24 - A Simple Cuff-Suture Technique for Microvascular Anastamosis

JACKIE BEHRING - Dec 08, 2025, 8:49 PM CST

Title: A Simple Cuff-Suture Technique for Microvascular Anastamosis

Date: 09/24/2025

Content by: Jackie

Present: N/a

Goals: Understand older cuff-based anastomosis methods that combine sutures with a supporting cuff structure to evaluate which features may inform or contrast with modern sutureless designs.

Content:

Overview

- Technique uses a soft silicone rubber cuff to simplify and speed up microvascular anastomosis
- Applied to end-to-end and end-to-side anastomoses in rats
- Intended to eliminate assistant requirement and reduce suturing complexity

Summary

- Silicone cuff: 2 mm wide, slightly larger diameter than vessel
- Proximal vessel slipped over cuff
- Three 10-0 nylon sutures placed around circumference
- Sutures used to evert vessel edge over cuff
- Distal vessel telescoped over proximal cuffed vessel
- End-to-side version: renal vein implanted into inferior vena cava (IVC) using a similar cuff-supported eversion approach
- Cuff divided into quadrants for suture placement

Results

- End-to-end anastomoses: avg. 6 minutes
- End-to-side anastomoses: avg. 7 minutes
- All 10 end-to-end anastomoses patent at necropsy
- End-to-side: 5 out of 6 rats survived; all survivors had patent anastomoses
- No intimal thrombi or foreign-body reactions
- Microscopy: normal vessel morphology, smooth intimal continuity, no degeneration
- Technique considered as fast as non-sutured methods at the time

Advantages

- Very rapid procedure
- Minimal foreign-body reaction
- Relies on simple, low-cost materials
- Reduces technical difficulty compared to full-suture methods

Limitations

- Still requires sutures
- Requires precise eversion and cuff placement
- Not fully sutureless
- Silicone cuff remains as a permanent implant

URL: https://www.thieme-connect.de/products/ejournals/pdf/10.1055/s-2007-1006735.pdf

Conclusions/action items: Use this cuff-suture method as a historical baseline to highlight how modern devices aim to remove sutures entirely and improve reliability, while retaining benefits like eversion support and minimized foreign-body response.

2025/09/26- Stent and Artery Geometry Determine Intimal Thickening Independent of Arterial Injury

JACKIE BEHRING - Dec 08, 2025, 9:00 PM CST

Title: Stent and Artery Geometry Determine Intimal Thickening Independent of Arterial Injury

Date: 09/26/2025

Content by: Jackie

Present: N/a

Goals: Understand how stent geometry and strut distribution influence neointimal thickening, thrombosis, and lumen shape to inform geometric choices in coupler/stent-like anastomosis devices.

Content:

Overview

- Study tested whether post deployment luminal geometry, dictated by stent design, influences intimal thickening independent of arterial injury.
- Stainless steel stents with 8 vs 12 struts implanted into rabbit iliac arteries.
- Goal: isolate geometry effects while keeping injury constant.

Key Findings

- 12-strut stents produced:
    - 50–60% less mural thrombus at 3 days
    - ~2× less neointimal area at 28 days
    - More circular lumen shape
- Strut number, not strut thickness, determined early thrombosis and late neointimal growth.
- Sequential histology showed thickening varies cyclically along the stent where lumen geometry changes.

Mechanism

- At deployment, vessel adopts a polygonal lumen, with each strut acting as a vertex.
- More struts → lumen closer to circular → improved flow, less turbulence/stagnation.
- Mathematical model accurately predicted neointimal growth using geometry alone.
- Suggests fluid dynamics and strain patterns, not injury, drive much of restenosis response.

Clinical Relevance

- Stent design (strut count + uniformity) strongly impacts biological response.
- More evenly spaced struts = smoother blood–tissue interface = reduced thrombosis + less intimal hyperplasia.
- Supports geometric optimization as a key factor in vascular implant design.

URL: https://www.ahajournals.org/doi/10.1161/01.cir.101.7.812

Conclusions/action items: Use this evidence to prioritize uniform circumference geometry and smooth internal flow paths in the coupler design, minimizing abrupt transitions or noncircular lumen shapes to reduce thrombosis and intimal thickening risk

JACKIE BEHRING - Dec 08, 2025, 8:57 PM CST

Stent and Artery Geometry Determine Intimal Thickening Independent of Arterial Injury

Abstract

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Stent_and_Artery_Geometry_Determine_Intimal_Thickening_Independent_of_Arterial_Injury___Circulation.pdf (1.81 MB)

2025/10/01 -Exploring the Role of Stent Strut Geometry in Cellular Behavior

JACKIE BEHRING - Dec 08, 2025, 9:03 PM CST

Title: Exploring the Role of Stent Strut Geometry in Cellular Behavior

Date: 10/01/2025

Content by: Jackie

Present: N/a

Goals: Understand how different stent-strut cross-section geometries directly influence cell morphology, proliferation, and ECM organization to guide safe geometric choices for future vascular implants.

Content:

Overview

- ISR persists despite drug-eluting stents; geometry suspected as a key driver of maladaptive healing
- Study isolates geometry effects using a PDMS chip platform mimicking 6 strut shapes
- Focuses on fibroblasts, early healing, and mechanobiology pathways

Geometries Tested (200 × 200 × 200 μm)

- Smooth: circle, oval, hexagon
- Sharp-cornered: rectangle, triangle, trapezium
- Figure 1 (page 6): diagrams show stent layout and six cross-sections

Model Fabrication

- Femtosecond laser writing + soft lithography
- PDMS molds produce arrays with 20 replicates per shape
- SEM and white-light interferometry confirm accuracy (Figures 3–4)

Key Biological Findings
Cell Morphology (24 hrs)

- Sharp shapes → elongated cells, flattened cytoskeleton, increased stress fibers
- Smooth shapes → normal spindle morphology
- Figure 5: confocal images show alignment and deformation around sharp corners

Cell Proliferation (3 days)

- Proliferation significantly higher at sharp-cornered shapes
- Example: trapezium > 70% EdU+ vs circle ~40%
- No difference for “no-contact” regions → highly localized geometric effect
- ROCK inhibitor eliminates differences → proliferation driven by intracellular tension (Figure 6)

ECM Organization (3 weeks)

- Sharp shapes → highly disorganized, isotropic fibronectin (low coherency values)
- Smooth shapes → more anisotropic, aligned ECM
- Figure 7: vector fields illustrate ECM disorder around sharp shapes

Mechanistic Insight

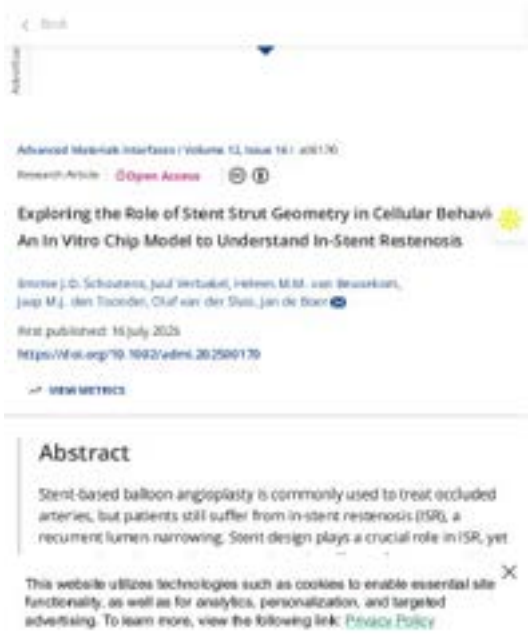
- Geometry-induced deformation elevates RhoA/ROCK mechanotransduction
- Sharp edges amplify tension and promote granulation-like response
- Cellular behavior consistent with clinical ISR patterns (sharper struts → more neointimal growth)

Limitations

- 2D platform; future work should extend to 3D tissue
- Real stent struts are elongated wires, not cube-like elements
- Cell communication across 300 µm spacing possible but effects remained localized

Conclusions/action items: Avoid sharp internal geometries in vascular implant designs; prioritize smooth, rounded contours to minimize local mechanotransduction-driven proliferation and reduce restenosis risk

JACKIE BEHRING - Dec 08, 2025, 9:04 PM CST


Exploring the Role of Stent Strut Geometry in Cellular Behavi
An In Vitro Chip Model to Understand In-Stent Restenosis
Abstract
Stent-based balloon angioplasty is commonly used to treat occluded arteries, but patients still suffer from in-stent restenosis (ISR), a recurrent lumen narrowing. Stent design plays a crucial role in ISR, yet
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Exploring_the_Role_of_Stent_Strut_Geometry_in_Cellular_Behavior__An_In_Vitro_Chip_Model_to_Understand_In_Stent_Restenosis.pdf (2.45 MB)

2025/10/03 - Self-expanding nitinol stents: material and design considerations

JACKIE BEHRING - Dec 08, 2025, 9:10 PM CST

Title: Self-expanding nitinol stents: material and design considerations

Date: 10/03/2025

Content by: Jackie

Present: N/a

Goals: Understand how nitinol's material properties and stent design parameters influence performance, expansion behavior, and chronic outward force to guide material selection for our adjustable cuff/stent device.

Content:

Overview

- Nitinol combines superelasticity, shape memory, and biocompatibility, making it ideal for self-expanding vascular stents.
- Properties cannot be replicated by other common stent metals.

Key Material Characteristics

- Shape memory effect: recovers pre-set shape when heated above transformation temperature.
- Superelasticity: large recoverable strains at body temperature; enables self-expansion.
- High corrosion resistance: comparable to stainless steel despite high nickel content.
- Excellent biocompatibility: suitable for permanent implants.

Design and Deployment Notes

- Stents are manufactured slightly larger than target vessel diameter.
- Delivered constrained; on deployment, they expand until contacting vessel wall.
- Provide low chronic outward force (COF) to avoid vessel trauma.
- Can resist external compression via high radial resistive force (RRF).

Performance Considerations

- Balance between COF and RRF is a central design requirement.
- Superelastic plateau allows controlled expansion and reduces risk of arterial injury.
- Fatigue resistance important for long-term durability in pulsatile environments.

Advantages of Nitinol for Anastomotic Devices

- Can accommodate diameter variability (matches your 2–5 mm requirement).
- Recovers shape reliably after deformation.
- Reduced risk of permanent deformation from surgical manipulation.
- Smooth expansion reduces intimal damage compared to rigid metallic devices.

Common Clinical Stent Designs Mentioned

- Examples include various braided or laser-cut nitinol stents; emphasis on geometric differences affecting radial force and flexibility (details not fully listed in abstract).

Conclusions/action items: Prioritize nitinol for the final device due to its superelastic expansion, biocompatibility, and ability to apply controlled outward force, and use these material principles to guide the cuff's expansion mechanism and safety thresholds.

JACKIE BEHRING - Dec 08, 2025, 9:10 PM CST

Self-expanding nitinol stents: material and design considerations

Abstract

Related information

LinkOut - more resources

Download

Self-expanding_nitinol_stents__material_and_design_considerations_-_PubMed.pdf (95.2 kB)

2025/10/14 - A Review on Manufacturing and Post-Processing Technology of Vascular Stents

JACKIE BEHRING - Dec 09, 2025, 1:41 AM CST

Title: A Review on Manufacturing and Post-Processing Technology of Vascular Stents

Date: 10/14/2025

Content by: Jackie

Present: N/a

Goals: Understand fabrication pathways and surface-treatment strategies for vascular devices to identify manufacturable, scalable processes relevant to our coupler design.

Content:

Stent Background / Generations

- BMS → DES → Bioresorbable stents (BDS)
- Complications motivating improved designs: restenosis, thrombosis, inflammation, stent fracture
- Increasing need for precision manufacturing and patient-specific geometry

Traditional metals

- 316L SS: strong, corrosion-resistant, poor flexibility → fracture risk
- NiTi (nitinol): good elasticity and shape memory; creates high internal stress in narrowed vessels
- CoCr: thinner struts possible; better radio-opacity and mechanical strength

Biodegradable metals

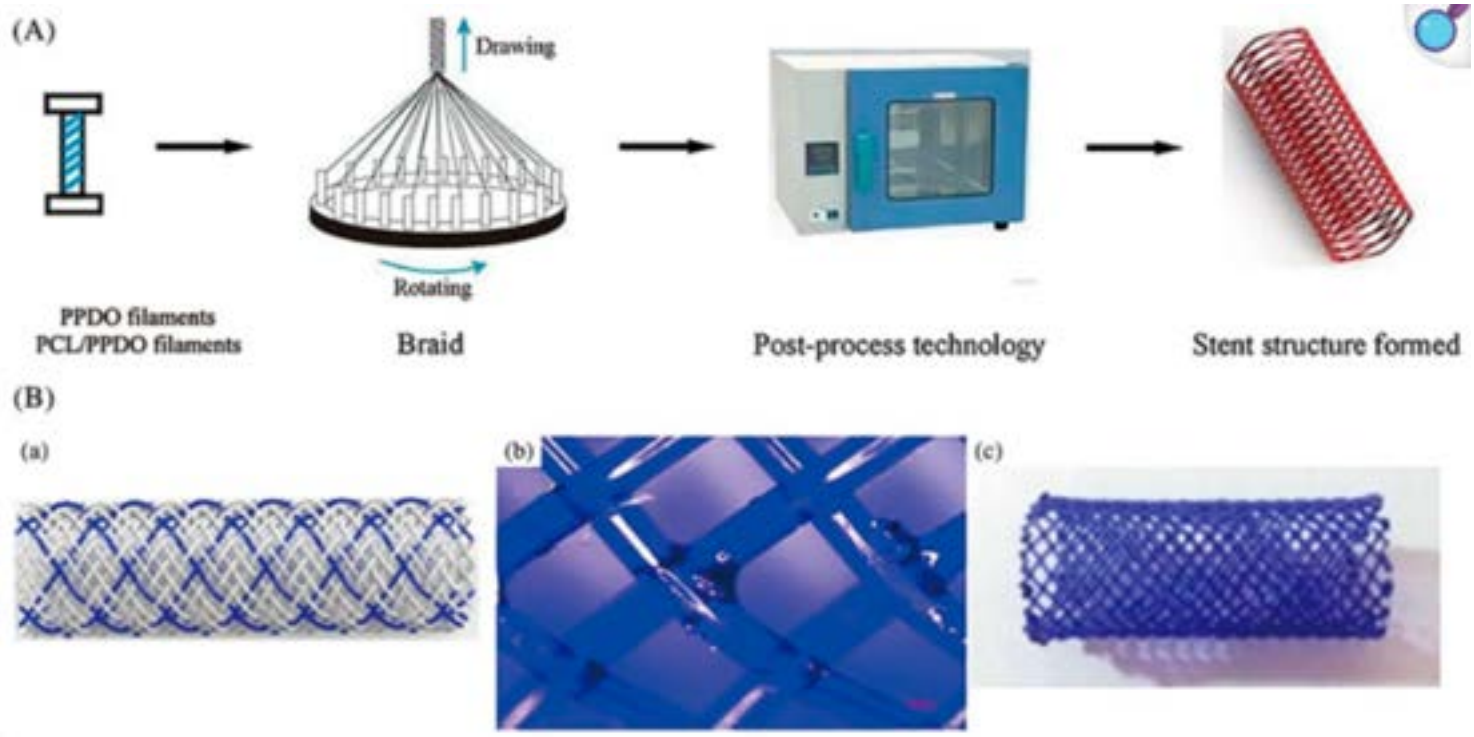
- Mg alloys: good strength; corrosion rate critical; Mg^{2+} concentration affects SMC behavior
- Zn alloys: promising corrosion profile; safe degradation (1–2 years)

Biodegradable polymers

- PLLA most common; good biocompatibility but limited mechanical strength
- Other polymers explored: PLGA, PCL, PGA, PDLA

Braiding

- Wire-based mesh structures; simple, compliant
- Limited radial stiffness; suited for polymer stents
- Image shows braiding equipment and final stent structure

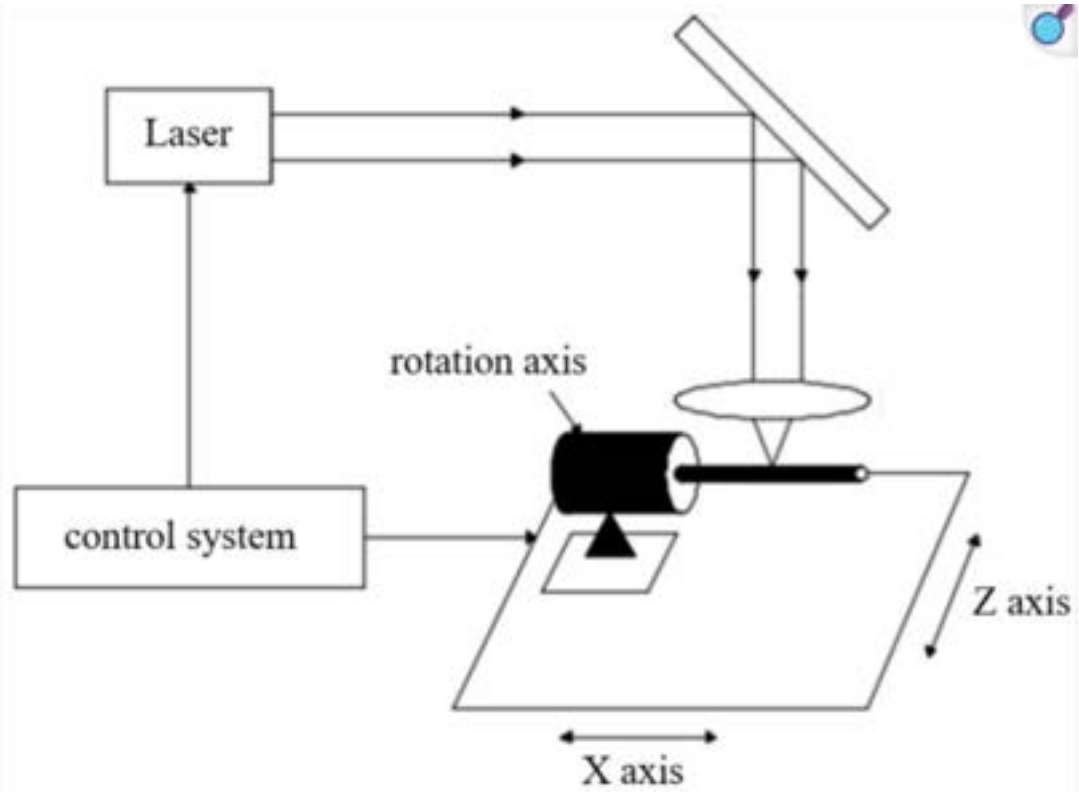


Micro-Injection Molding

- High throughput, excellent surface quality
- Hard to fill/demold complex micro-features
- Used for early polymer stent patents

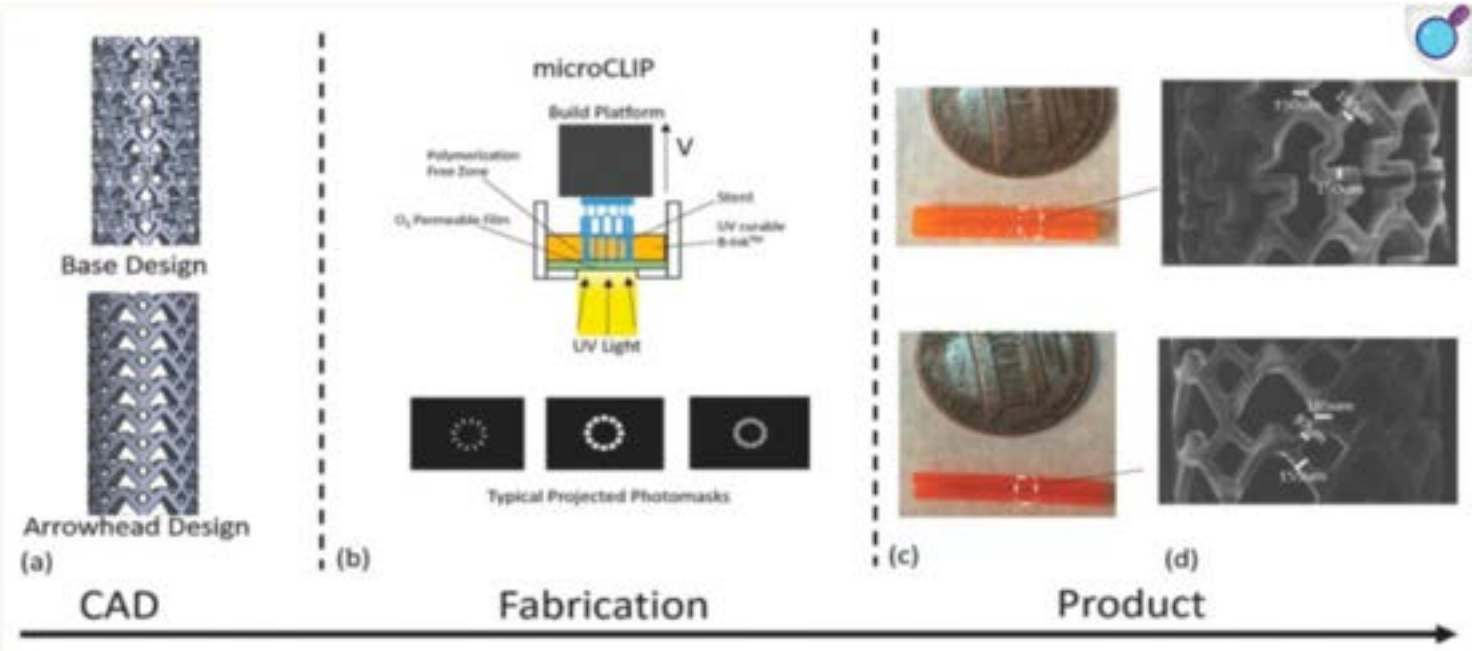
Laser Cutting

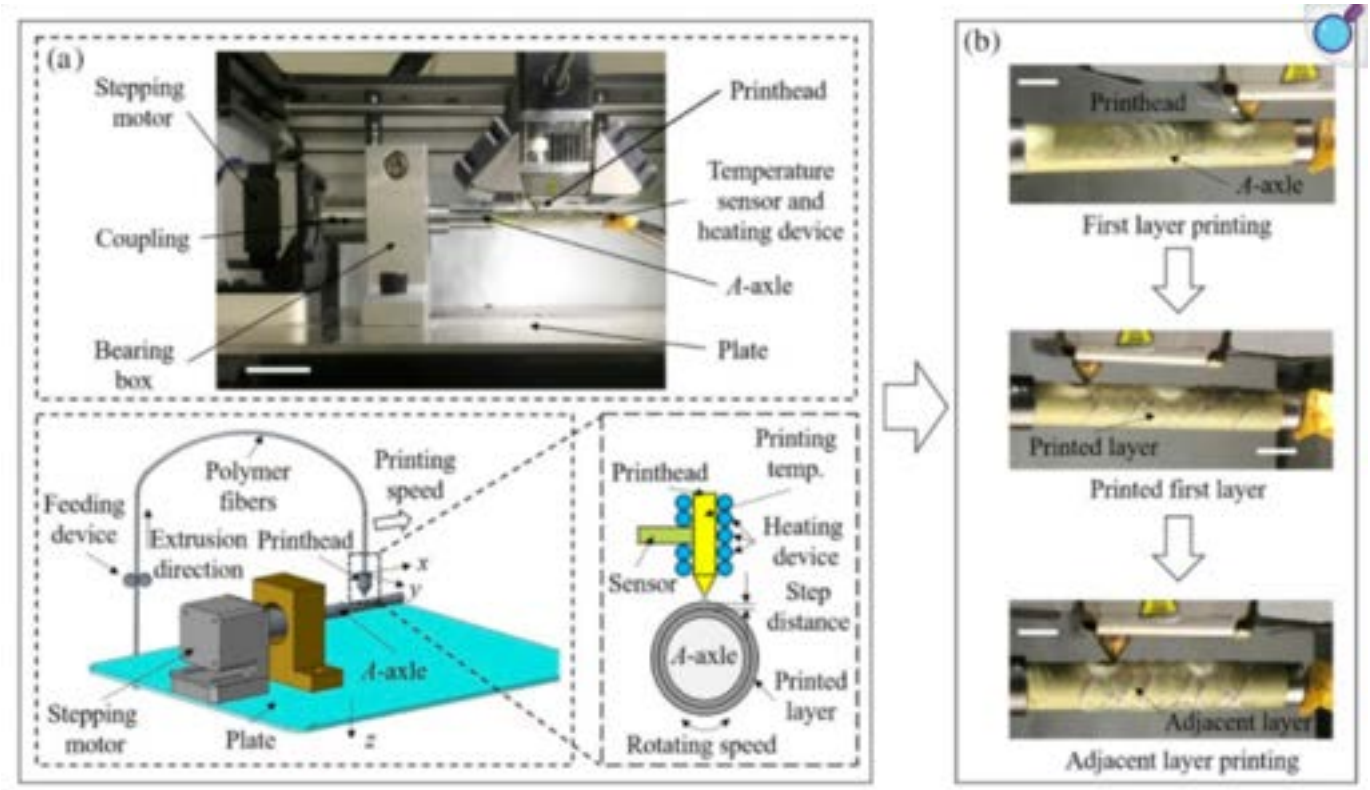
- Most common technique for metal stents
- High accuracy, adaptable to NiTi, SS, CoCr
- Challenges: heat-affected zone → worsens fatigue, corrosion, mechanical performance
- Numerous optimized approaches: femtosecond lasers, pulsed Nd:YAG, fiber lasers



3D Printing / Additive Manufacturing

- SLM for metal stents (CoCr, Fe alloys)
- μCLIP / SLA for high-resolution polymer stents
- FDM for PCL/PLA composite stents
- Enables personalized geometries, but accuracy still limited for fine struts



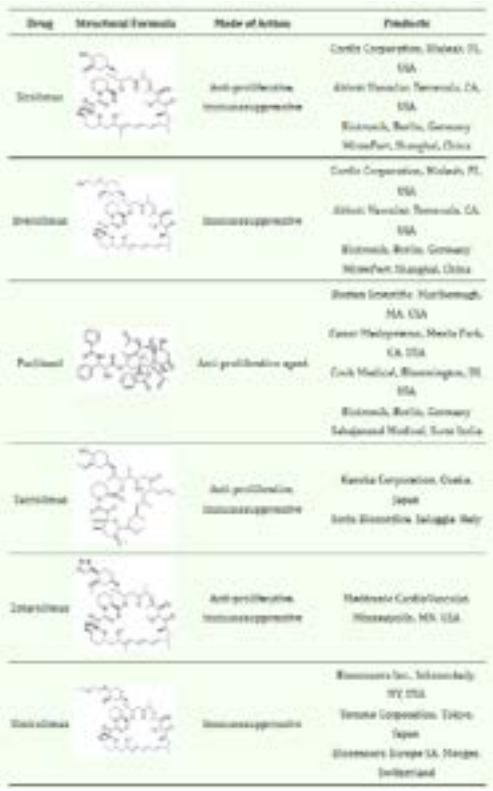


Other microfabrication methods

- μEDM, micro-photochemical etching, magnetron sputtering, precision milling
- Useful for thin-film TiNi devices and ultra-small diameters

Drug-Coating Strategies

- Purpose: reduce SMC proliferation, prevent thrombosis, control drug release
- Common drugs: sirolimus, everolimus, paclitaxel, tacrolimus, zotarolimus
- Methods: spray-coating, airbrush, ultrasonic coating, crystallization
- Micropore/microgroove reservoirs allow directional drug release



Surface Modification

- Chitosan/heparin, sulfated chitosan, hyaluronic-acid coatings
- Improves endothelialization and reduces thrombosis
- Layer-by-layer films enable selective cellular response

Surface Microstructures

- Grooves, pillars, laser-patterned features
- Influence hemocompatibility, drug loading, and endothelial cell migration
- NiTi micro-nano laser structures shown to reduce bacterial adhesion

Other finishes

- Polishing, oxidation, magnetoelectropolishing → improve corrosion/fatigue and biocompatibility
- Important for NiTi and CoCr devices

URL: https://pmc.ncbi.nlm.nih.gov/articles/PMC8778070/

Conclusions/action items: Select a manufacturing method that minimizes heat-affected damage

Micromachines (Basel). 2022 Jan 16;13(1):140. doi: 10.3390/mi13010140

A Review on Manufacturing and Post-Processing Technology of Vascular Stents

Wei Jiang [1], Wenxiang Zhao [2], Tianfeng Zhou [2], Liang Wang [1], Tianyang Qiu [2,*]

Editors: Young Jin Choi, Ge Gao, Hee Gyeong Yi

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PMCID: PMC8778070 PMID: 35057835

Abstract

Percutaneous coronary intervention (PCI) with stent implantation is one of the most effective treatments for cardiovascular diseases (CVDs). However, there are still many complications after stent implantation. As a medical

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2025/10/08 - Metal That Remembers Its Shape

JACKIE BEHRING - Dec 09, 2025, 1:14 AM CST

Title: Metal That Remembers Its Shape

Date: 10/08/2025

Content by: Jackie

Present: N/a

Goals: Understand practical engineering considerations, manufacturing challenges, and functional behavior of nitinol to inform feasibility and fabrication choices for our adjustable stent/cuff device.

Content:

Overview

- Nitinol discovered in 1959; now widely used in medical and aerospace applications.
- Known for shape memory and superelasticity, enabling devices like self-expanding stents.

Material Behavior

- Shape memory: deformable at low temperature; returns to pre-set form when heated above transformation temperature.
- Superelasticity: extreme elasticity just above transformation temperature; up to 30× elasticity of ordinary metals.
- Behavior caused by martensite ↔ austenite phase transformation.

Performance-Related Properties

- High fatigue strength; can withstand ~8% strain at body temperature and fully recover.
- Strong corrosion resistance from passive titanium-oxide layer.
- Good biocompatibility and kink resistance.
- Thermal/electrical conductivity lower than stainless steel.

Manufacturing Considerations

- Shape-setting requires heat treatment (~500°C) then rapid cooling.
- Surface finish critical for corrosion and biocompatibility performance.
- Very abrasive; causes significant tool wear.
- Carbide tooling recommended; EDM, water-jet, and laser machining effective.
- Material is expensive—cost must be justified by value added to device.

Applications

- Self-expanding vascular stents (see image on page 1: braided nitinol stent).
- Orthodontic wire, bone anchors, filters, heart valves.
- Aerospace: morphing engine components, actuators, landing gear systems.
- Robotics, sensors, appliances, fire-safety systems.

Engineering Caveats

- Use only when the application requires nitinol’s unique behaviors.
- Success depends on proper thermal processing and surface finishing.

- Working with experienced manufacturers improves final mechanical performance.

URL: https://www.asme.org/topics-resources/content/metal-that-remembers-its-shape

Conclusions/action items: Incorporate nitinol only where its superelastic expansion and fatigue resistance add clear functional value, and plan manufacturing around required heat-setting and surface-processing steps to ensure biocompatibility and mechanical reliability.

JACKIE BEHRING - Dec 09, 2025, 12:26 AM CST

Metal That Remembers Its Shape

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Metal_That_Remembers_Its_Shape_-_ASME.pdf (1.41 MB)

2025/10/10 - An Overview of the Nitinol

JACKIE BEHRING - Dec 09, 2025, 1:26 AM CST

Title: An Overview of the Nitinol

Date: 10/10/2025

Content by: Jackie

Present: N/a

Goals: Understand the phase transformation behavior of nitinol

Content:

Composition / Basics

- Nitinol = nickel–titanium alloy, roughly 50/50 atomic %.
- Exists in two temperature- and stress-dependent crystal structures: austenitic phase and martensitic phase

Austenite Phase - High temp

- Stable at high temperature.
- Stronger, stiffer crystal structure.
- Returns to pre-set “remembered” geometry when heated into this phase.
- Responsible for shape recovery after deformation.
- Activation via reverse transformation: *martensite → austenite*.
- Both Af (austenite finish) and As (austenite start) temperatures define when recovery occurs.

Martensite Phase - Low temp

- Stable at low temperature.
- Easily deformable; soft and twinned structure.
- Can undergo large strains without permanent damage.
- When heated above Af, deformed martensite reverts to austenite and regains original shape → shape memory effect.
- Transformation defined by Ms (martensite start) and Mf (martensite finish).

Phase Transformation Temps

- Ms: austenite begins → martensite
- Mf: austenite fully transformed → martensite
- As: martensite begins → austenite
- Af: martensite fully transformed → austenite
- Exhibits thermal hysteresis (As ≠ Mf, Af ≠ Ms).
- Alloy composition and heat treatment determine transformation window.

Shape Memory

- Occurs when material is cooled below Mf, deformed, then reheated above Af.
- Heat triggers martensite → austenite transformation, restoring original geometry.

- Mechanism = thermally induced phase transition.

Superelasticity

- Occurs when nitinol is above Af (in austenitic state).
- Stress causes localized formation of stress-induced martensite.
- Removing stress converts martensite back to austenite → large recoverable strain.
- High “elastic” strain capacity without heating.
- Does *not* follow Hooke’s law.

Phases for devices

- Control of Af determines whether device expands at body temperature.
- Martensitic flexibility enables device compression during loading.
- Austenitic rigidity provides final deployed strength.
- Transition hysteresis influences fatigue resistance and deployment timing.

Applications

- Stents rely on superelastic austenite at body temperature for self-expansion.
- Delivery systems utilize martensite (deformable phase) for catheter loading.
- Orthopedic wires exploit superelastic stress-induced martensite during bending.

Conclusions/action items: Use this information about Nitinol phases when researching

JACKIE BEHRING - Dec 09, 2025, 1:41 AM CST

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An_Overview_of_the_Nitinol.pdf (3.85 MB)

2025/10/21 - Nitinol Properties

JACKIE BEHRING - Dec 09, 2025, 9:45 AM CST

Title: Nitinol Properties

Date: 10/21/2025

Content by: Jackie

Present: n/a

Goals: Understand the key mechanical, thermal, and phase-transformation properties of nitinol relevant to vascular device design.

Content:

Composition

- ~50% nickel, ~50% titanium (atomic %)
- Formula: NiTi

Phase Transformation

- Two phases: austenite (high temp) and martensite (low temp)
- Critical temperatures: Ms, Mf, As, Af
- Thermal hysteresis between forward and reverse transformation
- Shape recovery occurs when heated above Af

Shape Memory Effect

- Deformable in martensite
- Recovers pre-set shape when heated into austenite

Superelasticity

- Occurs when nitinol is above Af in austenitic state
- Large recoverable strain (up to ~8%)
- Stress-induced martensite forms and reverts during unloading

Mechanical Properties

- Ultimate tensile strength: ~754–960 MPa
- Yield strength: ~560 MPa (austenite), ~100 MPa (martensite)
- Elastic modulus: ~75 GPa (austenite), ~28 GPa (martensite)
- Poisson’s ratio: ~0.30
- Elongation: ~15%

Physical Properties

- Density: 6.45 g/cm³
- Melting point: ~1310°C
- Thermal conductivity: low (~0.1 W/cm·°C)
- Electrical resistivity: 76–82 μΩ·cm

Biocompatibility & Corrosion

- Excellent corrosion resistance from TiO_2 layer
- Good biocompatibility despite high nickel content

Fatigue & Durability

- High fatigue strength
- Resists kinking and permanent deformation

Manufacturability

- Difficult to machine; abrasive surface
- Compatible with EDM, laser cutting, precision grinding
- Properties highly dependent on heat-setting and composition control

URL: https://www.chemistrylearner.com/nitinol.html

Conclusions/action items: Use nitinol when phase transformation and superelasticity offer functional advantages, and ensure transformation temperatures are tuned to achieve the desired deployment and in-vivo behavior.

JACKIE BEHRING - Dec 09, 2025, 9:45 AM CST

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Nitinol_Nickel_titanium_-_Properties_Uses_and_Composition.pdf (1.13 MB)

2025/11/13 - Overview of Laser Lithography

JACKIE BEHRING - Dec 09, 2025, 11:12 AM CST

Title: Laser Lithography Overview

Date: 11/13/2025

Content by: Jackie

Present: N/a

Goals: Understand the basics of laser lithography and how laser-based microfabrication differs from traditional photolithography.

Content:

Photolithography Overview

- Uses photosensitive polymer (photoresist) + opaque mask
- Exposed regions harden; masked regions remain soft → etch pattern
- Can create nanoscale structures for microelectronics
- Historically used lamps; semiconductor scaling pushed transition to lasers
- UV wavelengths common for small features

Laser Lithography Basics

- Works on same principle as photolithography but uses a laser as the exposure source
- Minimum feature size proportional to laser wavelength
- Depends heavily on beam quality and focusing optics
- Higher-power lasers increase speed but risk thermal damage
- Air absorbs very short wavelengths (<193 nm), limiting wavelength selection
- Beam instabilities (size/shape) can affect pattern uniformity

Benefits of Laser-Based Systems

- High precision for microstructures (MEMS, integrated circuits)
- Avoids some limitations of mask aligners
- More flexible in patterning compared to fixed-mask methods
- Solid-state lasers offer stability, reliable operation, and consistent beam quality

Novanta DPSS Systems

- Available wavelengths: 473, 532, 660 nm
- Hermetically sealed design + PowerLoQ feedback control → high beam stability
- Diffraction-limited beam → feature size limited by wavelength, not beam shape
- Power/current adjustable to minimize thermal load
- Compact form factor for integration into manufacturing systems

Key Technical Factors in Laser Lithography

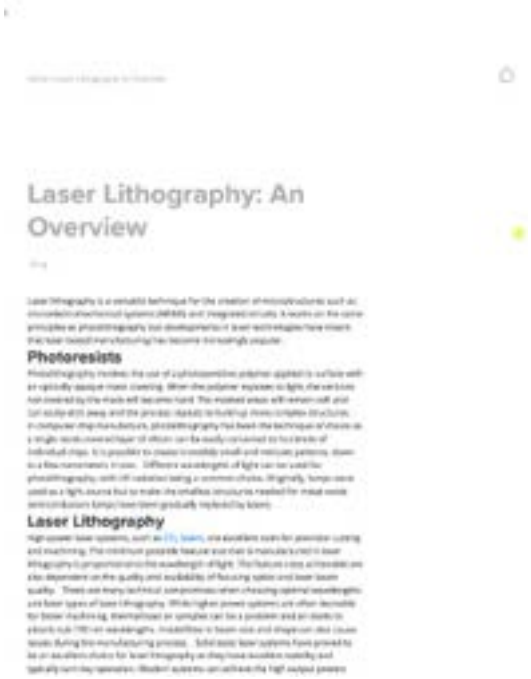
- Wavelength selection determines resolution

- Beam stability critical for consistent patterning
- Thermal management essential to prevent sample damage
- Focus quality and optics define final pattern fidelity

URL: https://novantaphotonics.com/laser-lithography-overview/

Conclusions/action items: Use laser lithography when precise, wavelength-limited microstructuring is needed and ensure laser wavelength, beam quality, and thermal control align with the intended resolution and material constraints.

JACKIE BEHRING - Dec 09, 2025, 11:12 AM CST



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Laser_Lithography__An_Overview.pdf (111 kB)

2025/11/18 - Lasers in Manufacturing

JACKIE BEHRING - Dec 09, 2025, 11:17 AM CST

Title: Lasers in Manufacturing

Date: 11/18/2025

Content by: Jackie

Present: N/a

Goals: Understand how different laser types and processing behaviors influence precision manufacturing options for micro-scale medical device components.

Content:

Overview

- Lasers are used for cutting, welding, surface treatment, drilling, structuring, and additive manufacturing.
- Common types include CO_2, Nd:YAG, fiber lasers, excimer lasers, and ultrafast (femtosecond/picosecond) lasers.
- Laser choice is driven by wavelength, pulse duration, power, material absorption, and desired feature resolution.

Laser Types

- CO_2 lasers (10.6 µm): strong absorption in organics and polymers; ideal for cutting plastics, wood, ceramics.
- Nd:YAG (1064 nm): widely used for metals; supports continuous or pulsed operation; good penetration depth.
- Fiber lasers: high beam quality, long lifetimes, and efficient for fine metal cutting; widely used for stainless steel and nitinol microfabrication.
- Excimer lasers (UV wavelengths): used for photochemical ablation with minimal thermal effects; suited for polymers and thin films.
- Ultrashort-pulse (femtosecond/picosecond) lasers: produce minimal heat-affected zone; capable of micro- and nano-scale precision features.

Advantages

- High accuracy and repeatability.
- Ability to cut very small, complex geometries.
- Non-contact process reduces mechanical stress on parts.
- Tunable energy input enables machining of difficult materials (e.g., metals, ceramics, polymers).
- Supports automation and high throughput.

Thermal Considerations

- Laser-material interaction depends on absorption and thermal conductivity.
- Continuous high-power lasers risk melting, microcracks, and recast layers.
- Shorter pulses reduce thermal diffusion and produce cleaner edges.
- For heat-sensitive materials (e.g., nitinol), pulse duration and wavelength significantly affect microstructure and fatigue life.

Applications

- Cutting of stents and fine metal tubes.
- Welding of precision joints.
- Surface texturing for adhesion, friction control, or wettability changes.

- Drilling micron-scale holes for filters, sensors, and fluidic devices.

Manufacturing Relevance

- Fiber or ultrafast lasers can cleanly cut thin-wall nitinol or stainless-steel cuffs.
- Laser texturing can introduce micro-features for vessel gripping or friction modifications.
- Minimizing heat-affected zones is critical for nitinol to preserve transformation temperatures and fatigue strength.
- Electropolishing typically follows laser cutting to remove recast and microburrs.

Conclusions/action items: Select a laser system that minimizes heat-affected damage while enabling fine-feature fabrication, and pair laser processing with smoothing or electropolishing to meet microsurgical safety and device-finish requirements.

JACKIE BEHRING - Dec 09, 2025, 11:18 AM CST

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Lasers_in_manufacturing.pdf (1.15 MB)

2025/11/27 - Laser Interference Lithography

JACKIE BEHRING - Dec 09, 2025, 11:23 AM CST

Title: Laser Interference Lithography

Date: 11/27/2025

Content by: Jackie

Present: N/a

Goals: Understand how surface engineering and nanostructuring improve nitinol's biocompatibility, corrosion resistance, and functional performance in biomedical implants.

Content:

Overview of Nitinol in Biodevices

- Nitinol widely used in stents, filters, orthodontic devices, and minimally invasive tools.
- Key benefits: superelasticity, shape memory, fatigue resistance, corrosion resistance.
- Challenges: nickel ion release, surface defects from manufacturing, need for controlled oxide layers.

Surface Engineering

- Reduce Ni ion release
- Improve corrosion resistance
- Enhance hemocompatibility and cellular response
- Increase fatigue life by reducing micro-defects
- Enable drug loading or functional coatings

Electropolishing

- Removes surface microcracks, recast layer, debris from laser machining.
- Produces smooth, uniform, corrosion-resistant surface.
- Decreases nickel release by forming stable TiO_2 layer.
- Common first-line finish for stents and nitinol implants.

Thermal Oxidation

- Creates controlled TiO_2-rich oxide layer.
- Improves corrosion resistance but must avoid excessive Ni diffusion.
- Higher temperatures risk phase transformation changes.

Plasma Treatments

- Plasma nitriding, plasma oxidation, plasma immersion techniques.
- Increase surface hardness, modify chemistry, improve wear resistance.
- Can tune hydrophilicity to enhance endothelial cell adherence.

Anodization

- Forms nanotubular or nanoporous oxide structures.
- Increases surface area, useful for drug loading.

- Nanotubes shown to promote endothelialization and reduce thrombosis.

Ion Implantation

- Introduces elements (e.g., nitrogen, carbon) into near-surface region.
- Enhances corrosion resistance, hardness, and fatigue behavior.

Coatings

- Polymer coatings (PTFE, parylene) for barrier protection.
- Drug-eluting coatings to reduce restenosis.
- Bioactive coatings (heparin, chitosan, HA) improve hemocompatibility.
- Nanocoatings enable directional drug release and cell-selective modulation.

Biocompatibility

- Surface roughness, oxide structure, and chemistry influence endothelial adhesion.
- Nanostructured surfaces promote controlled cell proliferation and reduced platelet activation.
- Smooth electropolished surfaces reduce thrombogenicity.

Manufacturing Considerations

- Laser cutting introduces defects → MUST be followed by electropolishing.
- Heat treatments must preserve Af temperature to maintain superelasticity.
- Surface treatments should avoid altering nitinol’s bulk transformation behavior.

Conclusions/action items: Use electropolishing as a baseline finish and incorporate controlled nanoscale surface engineering to enhance biocompatibility while preserving nitinol’s mechanical and phase-transformation properties

Laser Interference Lithography—A Method for the Fabrication of Controlled Periodic Structures

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nanomaterials-13-01818.pdf (13.1 MB)

2025/10/29 - PTFE Properties

JACKIE BEHRING - Dec 09, 2025, 10:35 AM CST

Title: PTFE Properties

Date: 10/29/2025

Content by: Jackie

Present: N/a

Goals: Understand the fundamental material properties of PTFE relevant to biocompatibility and engineering performance.

Content:

PTFE

- Synthetic fluoropolymer made of carbon–fluorine backbone
- Known commercially as Teflon
- Extremely low surface energy and non-stick behavior
- Smooth, low-friction surface (emphasized on page 1 image)

Key Properties

- Exceptional chemical resistance: stable against acids, bases, solvents
- Wide temperature tolerance: −260°C to +260°C
- Low friction coefficient: ideal for seals, bearings, moving interfaces
- Electrical insulation: maintains insulating ability across temperature range
- Biocompatible: classified USP Class IV; used in grafts, catheters
- Non-reactive surface: resists corrosion, degradation

Applications Mentioned

- Chemical processing equipment
- Aerospace and automotive components
- Electrical insulation systems
- Medical implants and tubing (vascular grafts, catheters)

URL: https://www.pbyplastics.com/blog/unveiling-ptfe-what-is-ptfe-material-and-its-remarkable-qualities#:~:text=PTFE%20is%20an%20excellent%20electrical,catheters%2C%20thanks%20to%20its%20biocompatibility.

Conclusions/action items: Use PTFE when low friction, chemical inertness, temperature stability, or biocompatibility are required, especially for components needing a non-reactive interface.

JACKIE BEHRING - Dec 09, 2025, 10:35 AM CST

Unveiling PTFE: What is PTFE Material

What Is PTFE Material?

The Remarkable Qualities of PTFE Material

1. Exceptional Chemical Resistance

2. High Temperature Range

Download

Unveiling_PTFE__Properties_and_Qualities.pdf (499 kB)

2025/11/06 - Material Properties

JACKIE BEHRING - Dec 09, 2025, 11:07 AM CST

Title: Material Properties

Date: 11/06/2025

Content by: Jackie

Present: N/a

Goals: Identify the quantitative mechanical and thermal properties of PTFE relevant to engineering and biomedical design.

Content:

General Properties

- Density: 2.14–2.20 g/cm³

Mechanical Properties

- Yield strength: 19.7–21.7 MPa
- Tensile strength: 20.7–34.5 MPa
- Elongation at break: 200–400%
- Vickers hardness: 5.9–6.5 HV
- Impact strength (notched): 1.5–1.7×10⁴ J/m²
- Fracture toughness: 1.32–1.8 MPa√m
- Young's modulus: 0.40–0.552 GPa

Thermal Properties

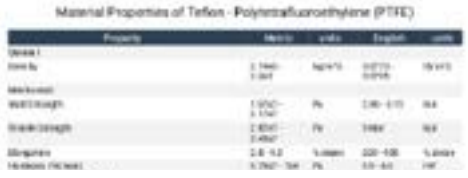
- Max service temperature: 250–271°C
- Melting temperature: 315–339°C
- Specific heat: 970–1090 J/kg·°C
- Thermal expansion coefficient: 1.2–1.7×10⁻⁴ /°C
- Electrical behavior: insulator

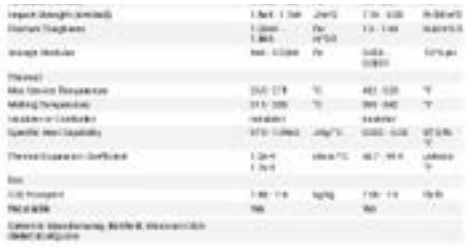
Environmental

- CO_2 footprint: 7.06–7.8 kg CO_2 per kg PTFE
- Recyclable: Yes

Conclusions/action items: Use PTFE when a low-strength, highly deformable, chemically inert, thermally stable, electrically insulating polymer is appropriate for the device interface or component.

JACKIE BEHRING - Dec 09, 2025, 11:07 AM CST





Download

Material_Properties_of_Teflon_-_Polytetrafluoroethylene_PTFE_.pdf (17.3 kB)

2025/12/03- SolidWorks Designs

JACKIE BEHRING - Dec 09, 2025, 11:35 AM CST

Title: SolidWorks Designs

Date: 12/03/2025

Content by: Jackie

Present: N/a

Goals: Upload all SolidWorks files

Content:

See attached

Conclusions/action items: Used these files for SolidWorks Testing and scaled up printing.

JACKIE BEHRING - Dec 09, 2025, 11:36 AM CST

Download

STENT_SMALL.zip (8.09 MB)

JACKIE BEHRING - Dec 09, 2025, 11:36 AM CST

Download

STENT_TALL.zip (5.12 MB)

2025/12/03 - Spike Stent Design

JACKIE BEHRING - Dec 09, 2025, 11:42 AM CST

Title: Spike Stent Design

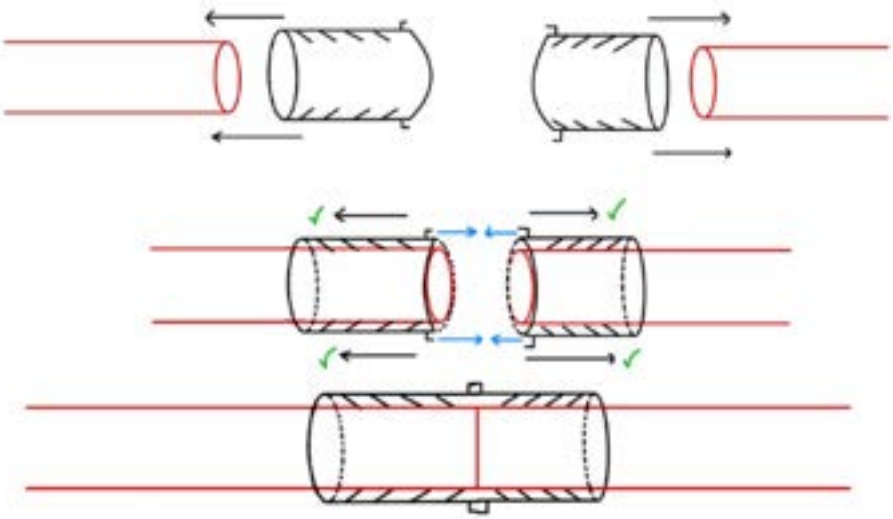
Date: 12/03/2025

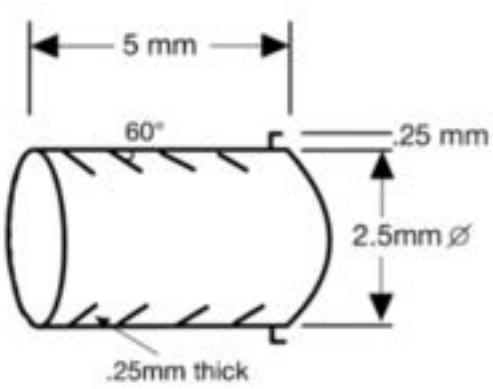
Content by: Jackie

Present: N/a

Goals: Upload spike stent design

Content:





Conclusions/action items: Utilize this design in the matrix.

2025/12/03 - Expandable Stent

JACKIE BEHRING - Dec 09, 2025, 11:44 AM CST

Title: Expandable Stent

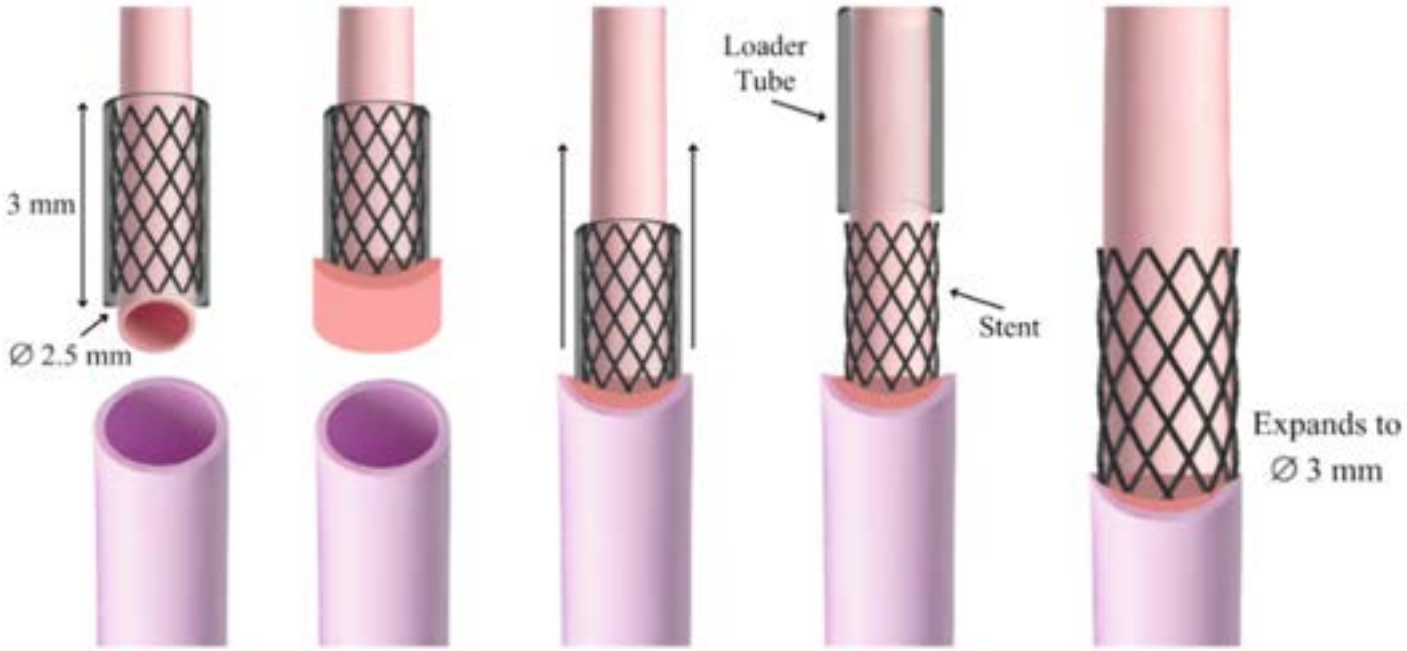
Date: 12/03/2025

Content by: Jackie

Present: N/a

Goals: Upload final prototype steps/design.

Content:



Conclusions/action items: Use this in the final report and as the final design.

2025/10/17-Training Documentation

JACKIE BEHRING - Oct 17, 2025, 5:08 PM CDT

Title: Training Documentation

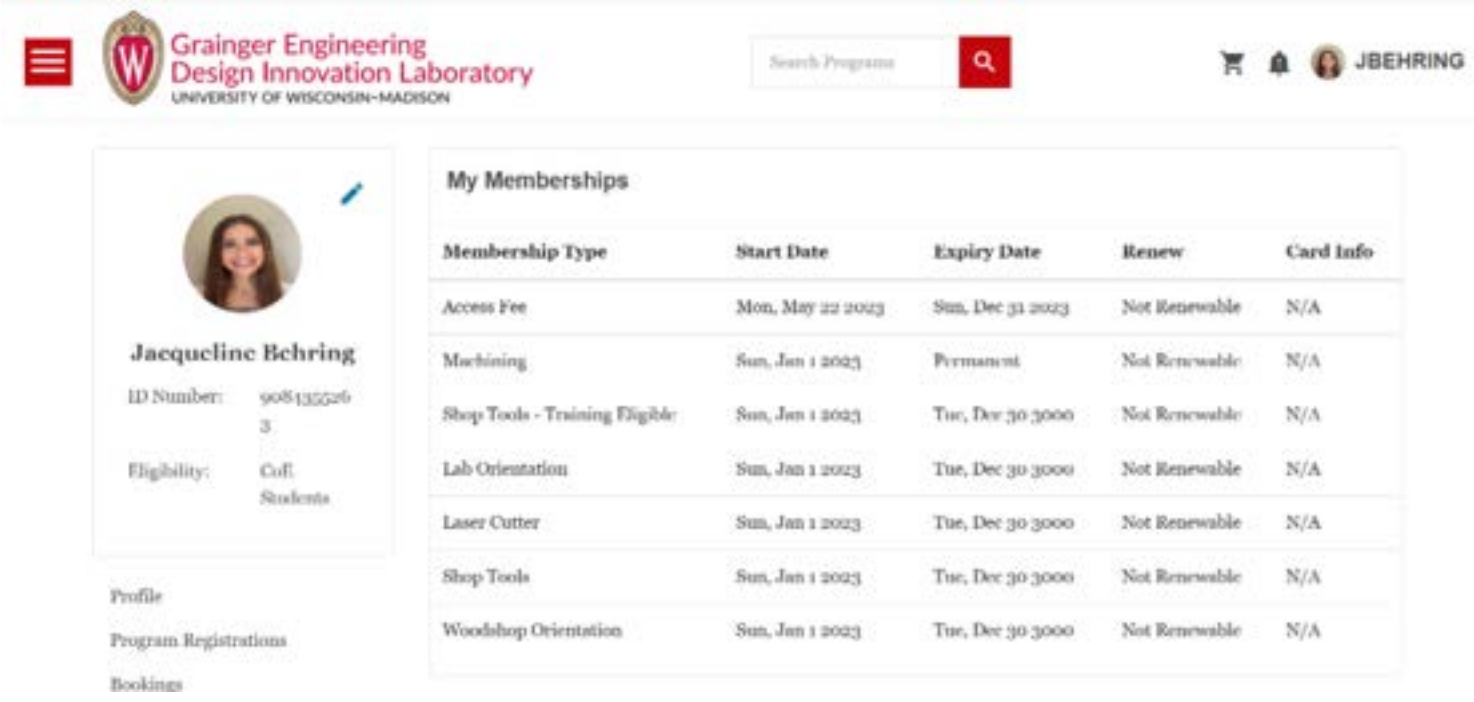
Date: 10/17/2025

Content by: Jackie

Present: n/a

Goals: Upload documentation of machine training. And complete new training on animal user orientation.

Content:



WISCONSIN
UNIVERSITY OF WISCONSIN-MADISON

This certifies that Jackie Behring has completed training for the following course(s):

Course	Assignment	Completion	Expiration
Biosafety Required Training	Biosafety Required Training Quiz 2024	1/25/2024	1/25/2029
Chemical Safety: The OSHA Lab Standard	Final Quiz	1/25/2024	

Data Last Imported: 10/17/2025 04:53 PM

Home / My Profile / Training Record

Training Record and Phones

Animal use status: **Expires on 10/17/2030**

Education ▾ Edit

Experience by Species ▾ Edit

Phones ▾

RARC Classes ▴

Completed

Class	Resources	Date
Animal User Orientation		10/17/25

Conclusions/action items: Use access to machines and training protocols for different aspects of the project. Animal training will benefit when using chicken thighs in anastomotic testing.

2025/09/09 - Cardiovascular fluid dynamics

SOFIA DECICCO - Sep 17, 2025, 10:58 PM CDT

Title: Cardiovascular fluid dynamics

Date: 09/09/2025

Content by: Sofia DeCicco

Present: n/a

Goals: The goal of this entry is to gain a better understanding of the cardiovascular fluid dynamics to help understand arterial vessels better

Content:

need for a solution: cardiovascular disease is the leading cause of death worldwide and fluid dynamics plays a central role in the functioning of the human cardiovascular system

- the heart pumps ~ once every second through blood vessels that have diameters as small as 3cm and 5um

Anatomical region	Mean Reynolds number	Peak Reynolds number	Womersley number
Ascending aorta	1000	4000–9000	19
Abdominal aorta	600	2500–4500	13
Coronary arteries	250	600–800	3
Carotid arteries	450	900–1200	4
Main pulmonary artery	1600	3000–4500	16
Arterioles	1	1	0.06
Capillaries	10^{-3}	10^{-3}	0.003
Inferior Vena Cava	400	1500–2500	13

The image above depicts the mean and peak reynolds number across multiple venous anatomical regions. A larger reynolds number indicated that inertial forces dominate over viscous forces which leads to more turbulent flow. With smaller reynolds numbers flow is smoother and more predictable.

- treatments guided by hemodynamic metrics have improved outcomes compared to anatomical imaging alone for cardiovascular diseases

Left ventricle:

- chamber of the heart that pumps oxygenated blood throughout the rest of the body --> thicker walls are required to drive this greater force output

1.) passive filling (diastole) the ventricular muscle is relaxed and oxygenated blood enters from the left atrium, mitral valve that connects the left atrium and ventricle is open (aortic valve remains closed).

2.) ejection (systole) occurs at the left ventricular pressure exceeds the aorta pressure causing the aortic valve to open and expel blood

Conclusions/action items: arteries can experience a varying degree of flow and this is modeled by the reynolds numbers in the image above. Since we will be working with micro arteries (2-3mm) the corresponding Reynolds numbers will be much lower - on a scale much smaller than 1.

2025/10/07 - Arterial Pressures

SOFIA DECICCO - Oct 17, 2025, 9:12 AM CDT

Title: Understanding Maximum Arterial Pressures

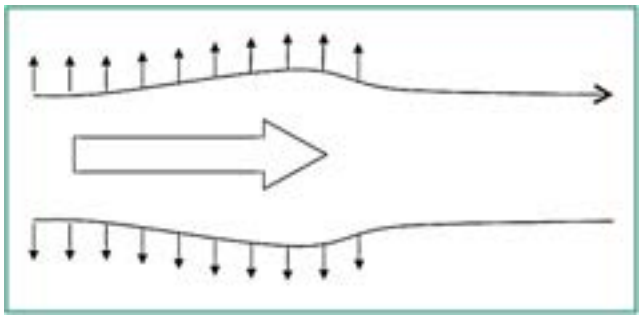
Date: 10/7/2025

Content by: Sofia DeCicco

Present: N/A

Goals: The goal of this entry is to find more literature supporting the maximum arterial pressure our device may be exposed to since this will likely exceed the average 80/120 mmHg during it's lifespan.

Content:



- When the heart contracts, the aortic valve opens and produces a pressure wave that will travel through the arteries. The arterial wall will dilate as a result of this pulse wave as it pumps blood forward.

In this article, to calculate arterial stiffness the following equations were utilized:

$$A = \pi(D/2)^2$$

$$\mathrm{DC} = \frac{\Delta A/A}{\Delta P}$$

$$\mathrm{CC} = \frac{\Delta A}{\Delta P}$$

$$\mathrm{Y} = \frac{D}{h} \times \frac{1}{\mathrm{DC}}$$

*assumed to be constant throughout the entire range of pulsatile arterial pressure values

D = the diastolic diameter of the artery, used to calculate A = surface area if the lumen

Delta A = systolic/diastolic variation in the section of the lumen (change in the transverse section of the vessel) - calculated by measuring the variation in diameter over time

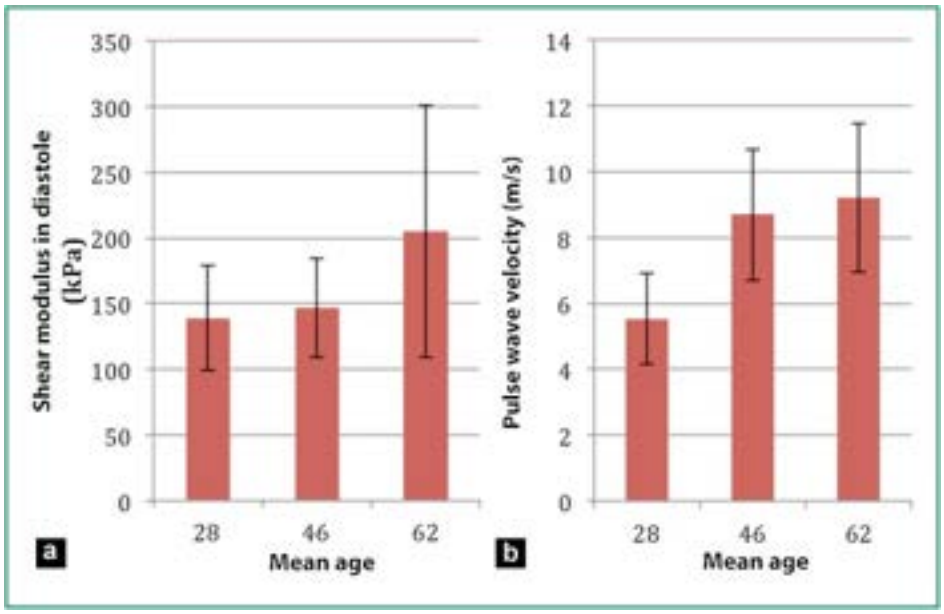
h = arterial wall thickness

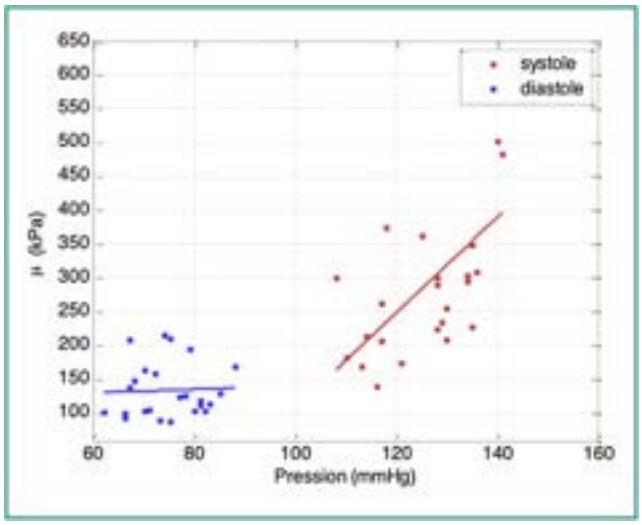
Delta P = variation in pressure

*DC = distensibility

*CC = compliance

Y = Young's modulus





Client specified that arterial pressures could reach 160-200 mmHg and the device should be suited for this application. The plot above models arterial wall stiffness in response to diastolic and systolic pressure changes. During systole, arterial pressures reached a maximum of 140 mmHg and this corresponded to a wall stiffness of 500 kPa. On the lower end, stiffness was recorded as low as 80 kPa in response to smaller diastolic pressures. The obtained diastolic stiffness measurements were separated into respective age groups. Across 30 patients the measured shear modulus increases with age most predominantly in the third age group that covers individuals 55-68 years old. Since the device does not have a target demographic, it must be compatible with a shear modulus ranging from 140 - 210 kPa.

Conclusions/action items:

From this research article, it is clear that arterial pressures and the elasticity of the arterial wall vary greatly during systole and diastole. Ultimately our device should withstand maximum pressures spanning from 160-200 mmHg and testing will consider arterial shear modulus of 140-210 kPa

2025/11/03 - Artery vs. Vessel

SOFIA DECICCO - Dec 10, 2025, 1:21 PM CST

Title: Anatomical Differences Between Arteries and Veins

Date: 11/3/2025

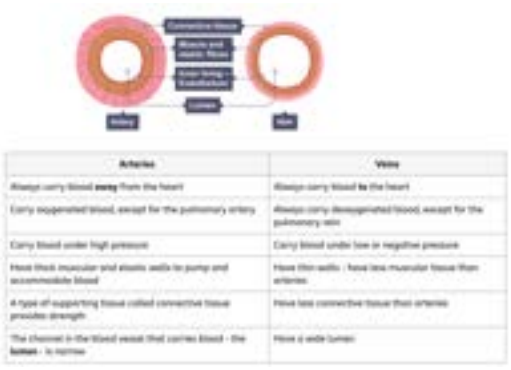
Content by: Sofia DeCicco

Present: N/A

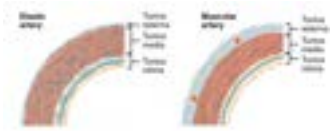
Goals: The goal of this entry is to understand the anatomical differences between arteries and veins to support the justification and clinical need for our device.

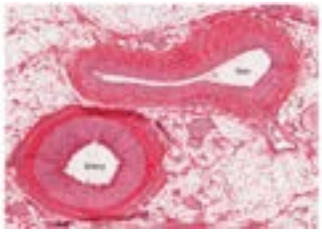
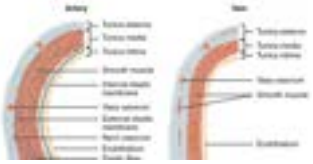
Citation: https://www.bbc.co.uk/bitesize/guides/zvjkbdm/revision/1, https://courses.lumenlearning.com/pgcc-ap2/chapter/structure-and-function-of-blood-vessels/#:~:text=Arteries%20transport%20blood%20away%20from,and%20vasodilation%20in%20their%20walls.

Content:



Arteries	Veins
Always carry blood **away** from the heart	Always carry blood **to** the heart
Carry oxygenated blood, except for the pulmonary artery	Always carry deoxygenated blood, except for the pulmonary vein
Carry blood under high pressure	Carry blood under low or negative pressure
Have thick muscular and elastic walls to pump and accommodate blood	Have thin walls - have less muscular tissue than arteries
A type of supporting tissue called connective tissue provides strength	Have less connective tissue than arteries
The channel in the blood vessel that carries blood - the **lumen** - is narrow	Have a wide lumen

Function	Vein	Artery
Direction of blood flow	carry blood toward the heart	carry blood away from the heart
Blood pressure and function	operate under low pressure, as blood has already passed through capillaries and lost much of its pressure by the time it reaches veins	operate under high pressure because they receive blood directly from the heart's pumping action
Wall thickness and structure	Veins have thinner walls overall their tunica media is thinner (less muscle/elastic tissue), which reflects the lower pressure environment.	Arteries have thick walls, especially a thick tunica media composed of smooth muscle and elastic fibers helps them withstand high pressure and to expand/ recoil with each heartbeat. 

Lumen size (internal passage for blood)	larger lumens- allowing them to hold a greater volume of blood at lower pressure.	smaller lumens- combined with thicker walls, this supports high-pressure flow
Shape and cross-sectional appearance 	Veins often appear irregular or collapsed/flattened, due to thinner walls and lower internal pressure	arteries tend to appear rounded because of their thicker, more rigid walls
Wall layer composition 	Both arteries and veins have the same three basic layers: tunica intima, tunica media, and tunica externa	

Conclusions/action items: Overall the artery varies greatly from vein in terms of shape, structure, and pressures. These will all be used in the justification for our design and design considerations.

2025/12/08 - Chicken Artery Models

SOFIA DECICCO - Dec 10, 2025, 1:02 PM CST

Title: Use of Chicken Arteries in Feasibility Testing

Date: 12/8/2025

Content by: Sofia DeCicco

Present: N/A

Goals: the goal of this entry is to understand the relevance of using chicken arteries to validate our design concept and how this transfer to human arteries

Citation: https://pmc.ncbi.nlm.nih.gov/articles/PMC7397825/#:~:text=Within%20the%20heart%20the%20tricuspid,2017).

Content:

Key reasons from the article in favor of using chicken arteries

- Anatomical and physiological similarity of heart/vessels between chickens and humans
- The study shows that the chicken heart, like the human heart, is four-chambered (right/left atrium and ventricle), with analogous major vessels and valves.
- major arteries and blood flow pathways in the chick are structurally analogous to those in humans
- Comparable vessel sizes and suitability for surgical / interventional testing
- Other research has found that certain chicken vessels have external diameters and muscular wall structure “comparable to human vessels”
- The fact that chicken arteries can fall within size ranges relevant to human small arteries suggests they are realistic for testing stent fit, insertion, eversion, and flow behavior.

Prior use of chicken arteries in vascular and atherosclerosis research

- Chickens have a long history as experimental vascular models, including for studying spontaneous or induced atherosclerosis
- Because of these prior uses, chicken arteries have been shown to respond to vascular injury, remodeling, and flow dynamics in a way that is informative for human vascular research.
- Chickens are small, readily available, and inexpensive compared to many large-animal models
- Their use simplifies logistical, ethical, and cost barriers, while still giving relevant insight into how an artery might behave in response to the device

Conclusions/action items: Given the anatomical similarity, comparable vessel size, and prior validated use in vascular research, chicken arteries provide a credible surrogate model for early-stage feasibility testing of the stent/tubing design

2025/09/17 - Suture-less Methods

SOFIA DECICCO - Sep 18, 2025, 11:19 AM CDT

Title: Sutureless anastomotic alternatives

Date: 09/17/2025

Content by: Sofia DeCicco

Present: N/A

Goals: The goal of this entry is to document sutureless methods for vascular anastomotic procedures and their impacts. This will help the team get an understanding of the current methods on the market and their strengths and limitations. From there, I can start sketching potential solutions taking these learnings into consideration.

Content:

Benefit of sutureless methods: expand global access to microvascular surgery, shorter operation time and ischemic times, and reduced costs. Due to the tedious nature of microvascular anastomosis accessibility is substantially reduced, sutureless methods can help expand reconstructive surgery worldwide.

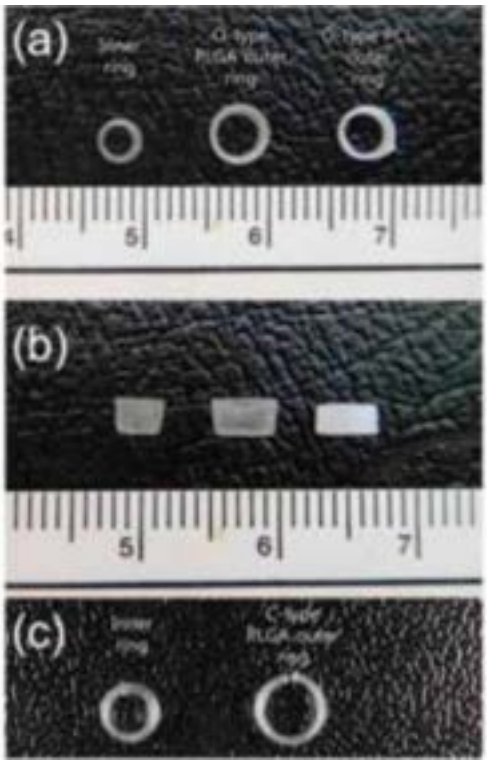
Following methods will be assessed by: artery compatibility, material composition, potential for intimal damage, risk of thrombosis and restenosis, deployment and maintenance.

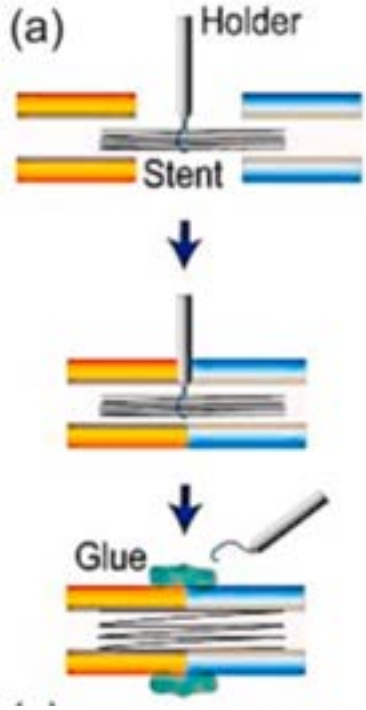
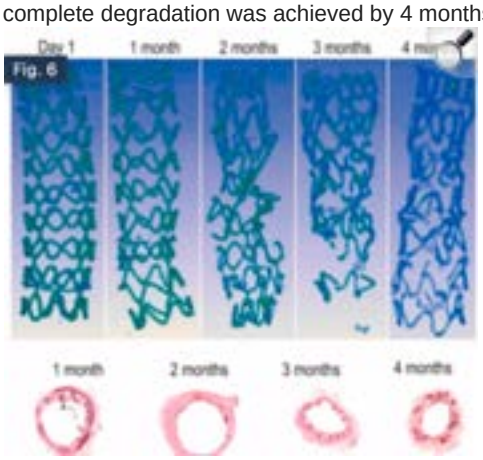
- Arteries have thicker media layers with a greater density of smooth muscle cells and elastin fibers. Thus arteries have greater elasticity compared to veins.
    - Increased elasticity + thicker media layer = decreased compliance

Vascular anastomosis allows surgeons to revascularize ischemic tissue and promote its survival. Vascular anastomosis has become a cornerstone of plastic and reconstructive surgery for its use in microvascular surgeries for flap transfer and tissue reconstruction.

FDA Approved Devices	Global Excellence in Microsurgery (GEM) Coupler	Developed by Synovis- the only sutureless device approved by FDA for microvascular anastomosis in free flaps Design for veins and arteries with a wall thickness below 0.5 mm Outer diameter ranges from 0.8mm - 4.3mm Results in intima-intima anastomis secured by pins  Has decreased anastomosis time by 20 minutes compared to had sewn techniques

		Complications requiring reintervention due to venous congestion were reduced 4.5% → 2.7% Decreased rate of failure rate compared to hand sewn (1.4% vs. 3.6%) in breast reconstruction. Failure being a revision, venous congestion, thrombosis • Time reduced from 21 minutes to 9.3 min Acceptance for arterial anastomosis remains limited. Arteries have thicker media layers than veins due to increased smooth muscle cells and elastin. This promotes higher elasticity that prevents rupture in a high pressured arterial vascular system. Increased elasticity and a thicker media lead to decreased compliance This inherent vascular nature of arteries makes them difficult to evert over the device!
Extraluminal Couplers: Decreased inflammation and minimal disturbance to natural blood flow Not exposed to blood and thus prevents an immune response Pitfall is the required eversion of vessels. Arteries being more elastic than veins prevents easy bending	Magnetic	Ventrica Magnet Coupler (VMC) is prominent device for end to side anastomosis VMC demonstrated that anastomosis with magnets is possible, but it requires substantial improvement in design to accommodate different arterial sizes and not alter natural arterial conformation 
	Absorbable	3D printing technologies: polyaprolactone (PCL), poly(lactic-co-glycolic acid) (PLGA), poly (l-lactide) (PLLA), and poly (l-lactide-co-ε-caprolactone) (PLCL) - high degree of biocompatibility Each of these materials have exhibited different degradation characteristics in vivo (PCL: 24–36; PLGA: 0.5–8; PLLA: 18–60; and PLCL: ∼6 months) A biodegradable coupler should maintain its integrity until the vessel heals and then degrade rapidly to minimize chronic inflammation while ensuring a robust anastomosis.

		
	Titanium/Plastic	Titanium has high biocompatibility and non-corrosive properties, making it an attractive choice for medical devices that are in prolonged contact with the human body - titanium does not degrade and may have long-term restenosis 
Intraluminal Stents	Metal alloy	NiTi is a common material choice because of its biocompatibility and its unique shape-memory ability Metal alloys provide unique advantages of biocompatibility, strength, and shape-memory, but

intraluminal stents pose the unique advantage of not requiring vessel eversion disadvantage of intraluminal stents is increased risk of thrombogenicity and inflammation		they pose potential for restenosis if anticoagulation/antiplatelet drugs are not used 
	Resorbable metal	Magnesium (Mg) and Zinc (Zn) as resorbable metal stents for vascular anastomosis Mg stent was treated with both chemical conversion coating and polymer coating to decrease the degradation rate Degradation of the stent began at 2 months, and complete degradation was achieved by 4 months 

Conclusions/action items:

Sutureless techniques for microvascular anastomosis have seen the greatest success with extraluminal couplers, such as the GEM coupler, which is widely used in venous anastomosis. However, despite their effectiveness in veins, similar devices for arterial anastomosis remain limited. A major barrier is the requirement for vessel eversion, which complicates their application in arteries. While extraluminal couplers reduce risk of thrombosis, their current designs do not adequately address the unique challenges of arterial repair, highlighting the need for innovation in this area.

2025/09/09 - Micro-anastomosis suture

SOFIA DECICCO - Oct 01, 2025, 8:17 PM CDT

Title: 2mm Vein End to End two-stay Suture Method

Date: 09/09/2025

Content by: Sofia DeCicco

Present: N/A

Goals: Watch a video of a micro-anastomosis surgical connection between two 2mm veins to better understand current treatment methods. Take note of any additional questions that arise to ask in client meeting.

Citation: https://youtu.be/yMw9DOjV9n4

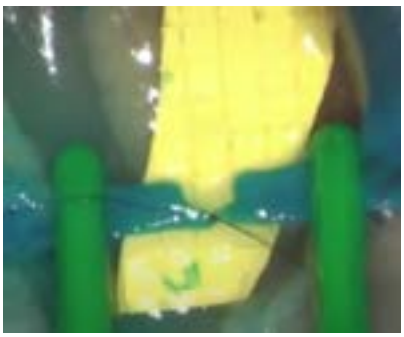
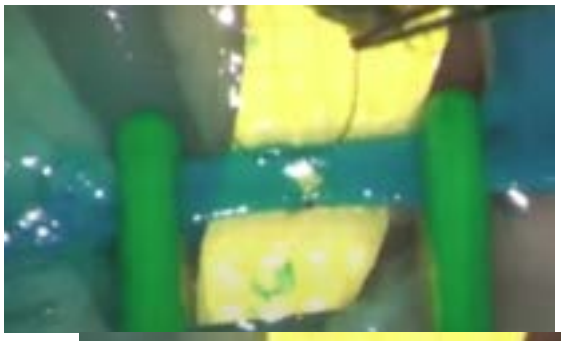
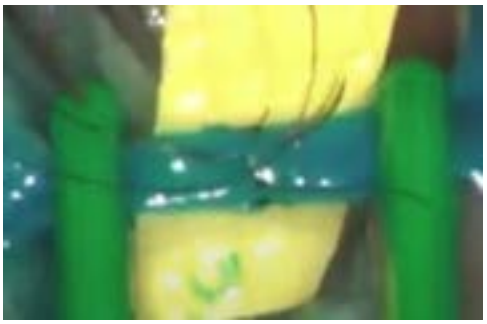
Content:

Attached is a video provided by out client on the one of the current surgical methods used for anastomotic surgery:

1. The first suture connection is made between the two veins at the edge

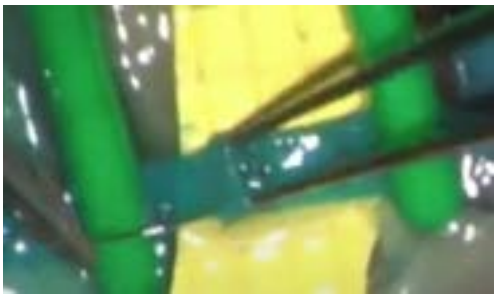
2. A second suture is attached at the other side (across the diameter) from the first stitch, currently resulting in two point of connection

3. Focussing on one side, restrained by the green clamps withholding blood flow, a more continuous "running stitch" pattern is added. A total of three stitches are formed.


4. The clamps are reversed to reveal the other side of the vein

5. On the reverse side an additional 3 sutures are made similar to the prior side


Conclusions/action items: It was very beneficial to see one of the current methods our client uses to perform a micro-anastomotic surgery. This video was taken in real time and took approximately 3:55 minutes. You can see how tedious this work is and how it will take a very experienced individual to perform the operation efficiently and safely. A 2mm artery is the scale we will be working at so this is a good visual representation of an area where our device may be applied.

2025/10/13 - Nitinol Geometry

SOFIA DECICCO - Dec 10, 2025, 12:21 PM CST

Title: Nitinol stent geometry considerations

Date: 10/13/2025

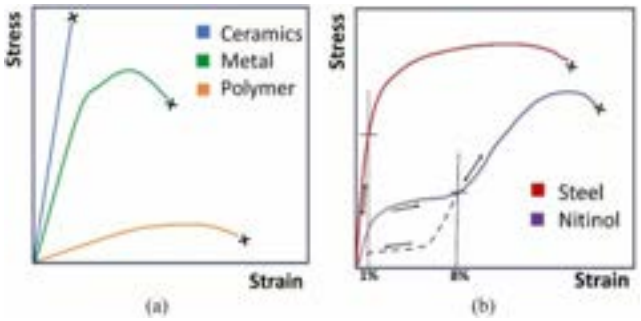
Content by: Sofia DeCicco

Present: N/A

Goals: The goal of this entry is to understand the important consideration for nitinol stent application and the role stent geometry has with changing these values

Content:

The nitinol stents discussed in this article are for treatment of atherosclerosis hardening and narrowing for blood vessels due to plaque buildup)

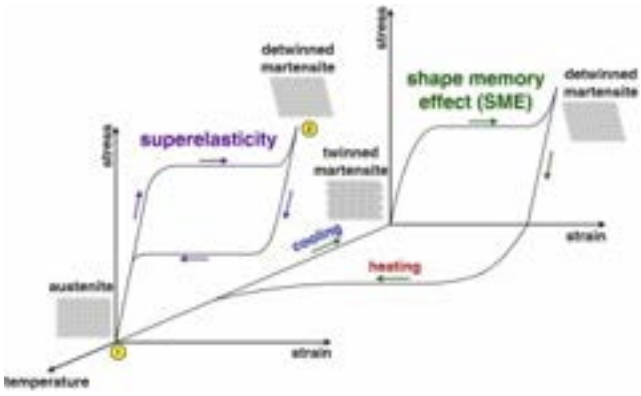


NiTi is the most effective material choice for self-expanding stents since the material choice must be able to undergo large deformation and have a low elastic modulus. → allows for a crimp into a sleeve for delivery

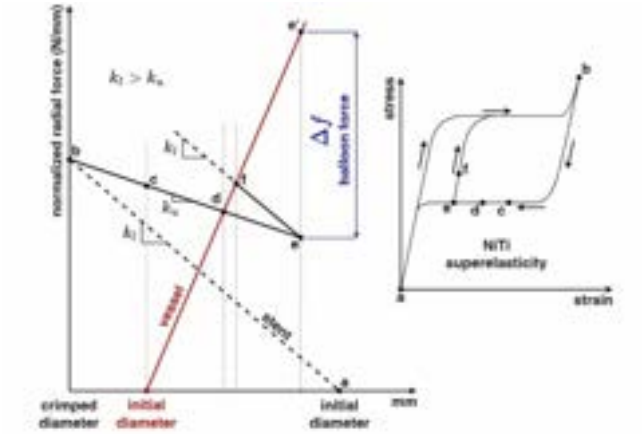
Superelastic behavior allows nitinol material to reach large elastic deformations above 8%

2 phases:

1. Austenite phase (parent phase):stable under low stress and high temperature
2. Martensite (daughter phase): stable under high stress and low temperature
    a. Twinned martensite: has twin boundaries making the material less stable. Stable at both low-stress and low temperatures
    b. Detwinned: martensite crystals have undergone a process that removed the twin boundaries and results in a more stable microstructure. Stable at high stress state regardless of temperature



Superelastic mechanical properties of NiTi are only evident within the temperature range between the austenite finish and determined martensite deformation temperatures

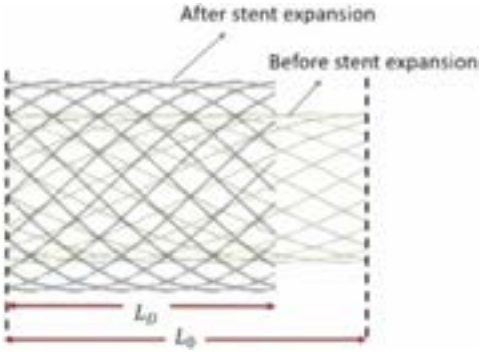


Path	Force-displacement diagram	Stress-strain diagram
a → b	Minimum stent diameter, max force reached with k_l stiffness	First loading phase, max stress and strain
b → c	Stent deployment, force decrease with k_l stiffness, onset of vessel impingement	Unloading following lower stiffness branch
c → d	Stent and vessel reach a first equilibrium point in d (before balloon angioplasty)	
d → e / e'	Balloon inflation, vessel expansion to point e', stent expansion to point e	
e / e' → f	Balloon deflation, vessel and stent reach last equilibrium point	Second loading phase due to vessel elastic spring back

The manufacturing techniques that are commonly used are the braiding technique, microinjection molding, laser cutting, and recently additive manufacturing

Key mechanical characteristics and performance indicators for nitinol stents

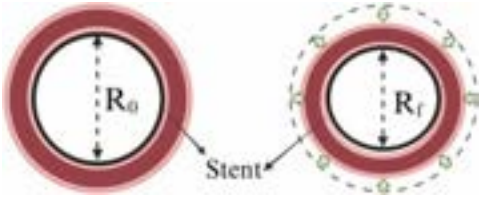
Foreshortening:



$$Foreshortening = \frac{L_0 - L_D}{L_0}$$

- Expansion of stent in the radial direction shortens the stent in the axial direction, called foreshortening
- Big consideration for the final length we would like the stent to achieve

Radial elastic recoiling

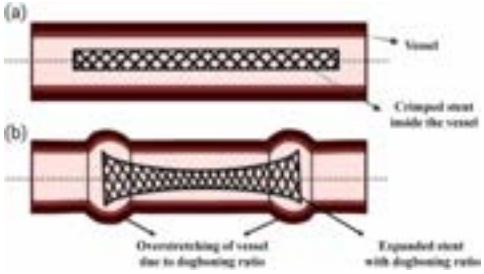


$$R_{recoil} = \frac{R_0 - R_f}{R_0}$$

- Pressure of vessel wall that is everted over the stent will oppose expansion of the stent
- If stent has high elastic recoil it will lack the ability to adequately support the blood vessel and maintain patency

- Targeted values is zero or lowest possible value
-

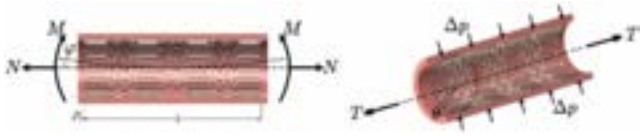
Dogboning



$$D_b = \frac{D_{distal} - D_{central}}{D_{distal}}$$

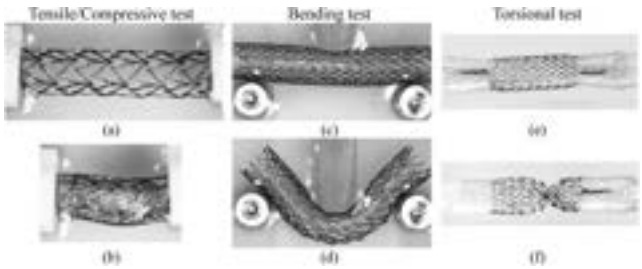
- Due to the fact that the proximal and distal parts of the stent are less stiff than the central area
- Target values is zero or <0

Stiffness



- Stent is exposed to axial, bending, torsional, and radial forces

Axial stiffness test methods:

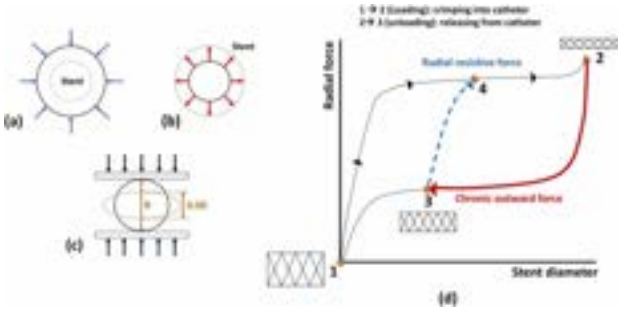


- Bending test: three-point bending
- Torsional stiffness test: restrict axial deformation and executing tests with different angles or angular displacement rotations in clockwise and counterclockwise directions

Oversizing:

- For application inside the artery: oversizing ratios are in the range of 1.1-1.4 to improve lumen gain, reduce incomplete stent apposition, and favorable long-term fatigue performance
- Too high of oversizing can result in high radial forces that can cause damage to the artery wall and comprise the stents long term efficacy
- Over sizing (OS) = initial stent diameter/vessel inner diameter

Radial forces:



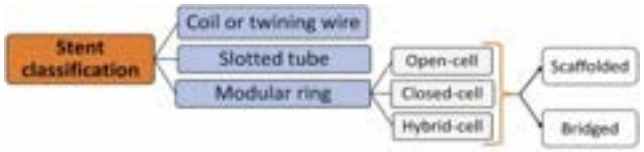
- Radial resistive force (RRF): the force required to compress the stent to a smaller size that will allow for the crimped application
- Chronic Outward Force (COF): the force that the stent exerts of the vessel wall when it undergoes expansion (during unloading)
- Crush resistance (CR): force required to crush the stent in the radial direction between parallel plates until there is a 50% diameter reduction

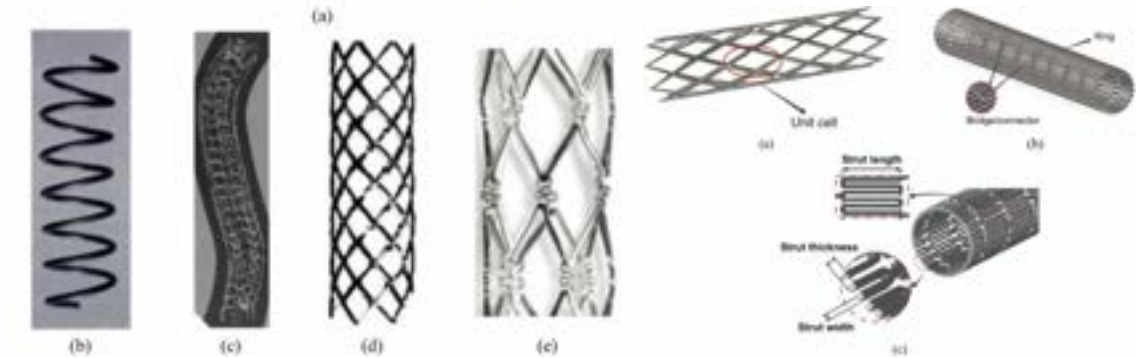
Summary of parameters and desired values:

Table 1. Desired values for SX NiTi stents.

Figures of merit (unit)	Desired value	References
Foreshortening (%)	Minimum the best	[7], [8]
Radial elastic recoil (%)	Minimum the best	[67]
Dogboning (%)	Minimum the best	[65]
Radial stiffness (MPa)	Nominal the best	[48], [81]
Axial stiffness (N/mm)	Minimum the best	[48]
Bending stiffness ($N \bullet mm/rad$)	Minimum the best	[8], [48]
Torsional stiffness ($N \bullet mm/rad$)	Minimum the best	[48]
Oversizing (%)	$10\% < OS < 40\%$	[82], [83], [84], [85]
Radial resistive force (N)	Nominal the best	[48]
Chronic outward force (N)	Minimum the best	[28], [48]
Crush resistance (N)	Maximum the best	[87]
Fatigue life (number of cycles)	Maximum the best	[20], [79], [110]
Wall shear stress (Pa)	Minimum the best	[97], [100], [111]

Stent Geometry:



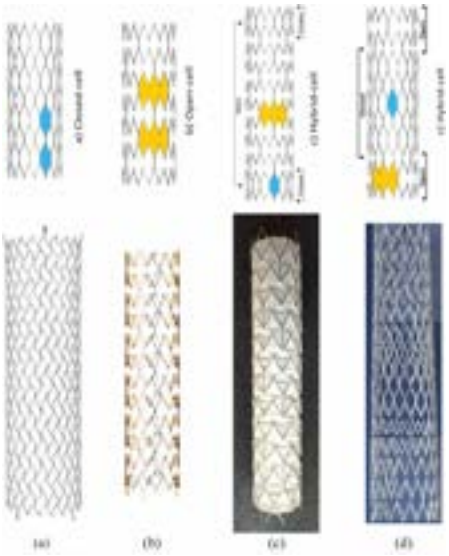


- Coil or twining wire: constructed using wires that are shaped and arranged into a circular coil configuration to form the stent scaffold
- Slotted tube: metal tube acts as the stent's basis material, and a specific design or pattern is generated using laser cutting (d)

- Modular ring: provides a balance between the bending compliance of coils and the radial strength of slotted-tube designs (e)
    - Closed-cell: characterized by interconnected stent strut with smaller free cell area, while the open-cell designs (shown in Fig. 15b) have larger free cell area with fewer interconnections
    - Open-cell:
    - Hybrid-cell: open-cell design in the central part, for improving the bending compliance of the stent, and a closed-cell design at the two ends to adjust the stiffness in the distal parts
    - Scaffold or bridged structures: rings play a pivotal role in radially expanding and providing support to the blood vessel, while bridges/connectors connect the rings axially, contributing to the stent's axial stiffness
- More gaps between the cells in an open-cell design makes it more compliant compared to a closed-cell design, which is particularly advantageous for complex arteries with angular or twisted anatomies
- closed-cell design has more interconnections, it is stiffer, offering better plaque coverage and structural support

Table 2. Comparison of parameters between open-cell and closed-cell stent designs.

	Open-cell stents	Closed-cell stents
Compliance	↑	↓
Radial stiffness	↓	↑
Applicability for complex vessel	↑	↓
Plaque coverage	↓	↑
Higher risk of restenosis	↓	↑
Velocity of blood flow after stenting	↓	↑



Conclusions/action items: This article provides great metric that can used by the team to understand how adjustments in design parameters can impact the mechanical properties of our final stent

2025/10/27 - GEM Coupler

SOFIA DECICCO - Dec 10, 2025, 1:54 PM CST

SOFIA DECICCO - Dec 10, 2025, 1:57 PM CST

Title: GEM Coupler

Date: 10/27/2025

Content by: Sofia DeCicco

Present: N/A

Goals: the goal of this entry is to understand how the current coupling device for vessels works and connect any transferable techniques to our design considerations for an arterial coupler

Citation: https://www.synovismicro.com/html/products/gem_microvascular_anastomotic_coupler.html

Content:

The GEM Coupler is a mechanical anastomosis device designed to join small arteries or veins (microvascular vessels) instead of using traditional hand-suturing

- It is intended for peripheral vascular system use (small vessels in microsurgical procedures)
- coupler consists of two ring-shaped components with stainless-steel pins; vessel ends are everted over the pins and held in place to create the anastomosis.
    - The rings are made of polyethylene, and pins are surgical-grade stainless steel

- Comes in multiple sizes (e.g., 1.0 mm, 1.5 mm, 2.0 mm, 2.5 mm, up to 4.0 mm couplers).

Device use:

- single-use, sterile
- Designed for vessels with outside diameter between 0.8 mm and 4.3 mm
- Intended for vessels with wall thickness ≤ 0.5 mm
- providing a faster and safer method compared to hand suturing
- less intraluminal foreign material: since there is no suture inside the lumen, lower risk of thrombosis
- better for joining vessels with different diameters than conventional suturing.
- The elasticity and degree of vessel spasm must be considered when selecting the correct coupler size

Conclusions/action items: This device is the current alternative to hand suturing techniques that is only limited to use for vessel. Design components from this can be used in the consideration for an arterial device. The limitations arise from the more elastic and thicker wall of arteries that will limit our ability to use spikes for eversion.

2025/09/17 - Standards and Specifications

SOFIA DECICCO - Dec 10, 2025, 2:37 PM CST

Title: Standards and Specifications of Anastomotic Coupler Devices

Date: 09/17/2025

Content by: Sofia DeCicco

Present: N/A

Goals: The goal of this entry is to identify the standards and specifications that will pertain to an arterial anastomosis device. The content from this entry will contribute to the PDS and future work that requires an understanding of the regulatory path forward.

Citations:

[1] C. for D. and R. Health, “Classify Your Medical Device,” FDA. Accessed: Sept. 17, 2025. [Online]. Available: https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device

[2] “510(k) Premarket Notification.” https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?id=K093310&utm

[3] B. Huzum et al., “Biocompatibility assessment of biomaterials used in orthopedic devices: An overview (Review),” Exp. Ther. Med., vol. 22, no. 5, p. 1315, Nov. 2021, doi: 10.3892/etm.2021.10750.

[4] “ISO 13485,” Amtivo US. Accessed: Sept. 17, 2025. [Online]. Available: https://amtivo.com/us/iso-certification/iso-13485/

[5] “ISO 14971 Risk-Management Compliance Quick Guide,” MasterControl. Accessed: Sept. 17, 2025. [Online]. Available: https://www.mastercontrol.com/resource-center/documents/iso-14971-2019-compliance-requirements

[6] “ISO 11135:2014,” ISO. Accessed: Sept. 17, 2025. [Online]. Available: https://www.iso.org/standard/56137.html

Content:

Current Microvascular Anastomotic Coupler Devices on the market are classified as Class II medical devices. The regulatory controls for Class II devices include general controls, special controls, and premarket notification 510(k). If the proposed composition of the biomaterial is substantially equivalent to a predicate device that is active on the market it can gain approval. If not, clinical trials are required for premarket approval [1].

- There is a classification of medical devices under “Anastomotic Microvascular” that may have devices that can be used as predicates [2].

The International Organization for Standardization (ISO) has a couple of standards that apply to the development of an arterial anastomosis device:

ISO10993 ensures the biological compatibility of a medical device ensuring nontoxic, nonthrombogenic, noncarcinogenic, and nonmutagenic effects on the biological system [3]. The device will be positioned on the outside of the arterial wall so contact with the blood and risk of clotting will likely not be a concern. Therefore the team will have to ensure nontoxic effects between the device, external wall, and surrounding tissue and skin.

ISO13485 requires that medical devices are monitored by quality management systems. Objective of the standard ensures production of a medical device and related services that meet customer requirements consistently [4].

ISO14971 applies risk management monitoring to the design, manufacturing, and life cycle of a medical device [5]. This would apply to mitigating vessel trauma, migration, and possible infection.

ISO11135 monitors the sterility and packaging requirements for the device being exposed to ethylene oxide sterilization [6]. If Eto is the method of sterilization we decide for our device, this will be a standard that will apply to final design requirements.

Conclusions/action items:

Overall, there are a number of ISO and FDA regulations that apply to arterial anatomic devices. From a regulatory and quality management perspective, ISO 14971 and ISO 13485 set these standards respectively. When considering shelf life and device storage, ISO11135 relates to ethylene oxide sterilized devices and ISO 11137 refers to radiation sterilization. ISO10993 will always be an important regulation for any device interacting with the biological system. Predicate anastomotic coupler devices exist that may allow our device to pursue the FDA's 510(k) clearance pathway.

2025/09/22 - Defining Biocompatibility

SOFIA DECICCO - Dec 10, 2025, 1:35 PM CST

Title: Biocompatibility assessment of biomaterials used in arterial devices

Date: 09/22/2025

Content by: Sofia DeCicco

Present:

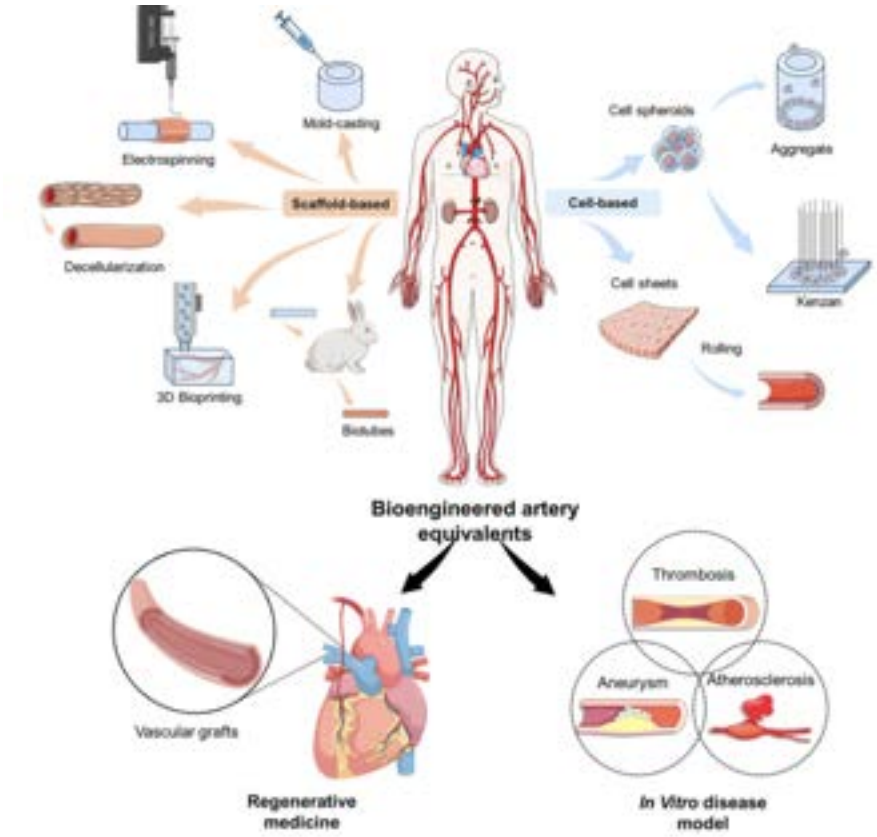
Citation: https://doi.org/10.3892/etm.2021.10750., https://www.sciencedirect.com/science/article/pii/S2589004224024404

Goals: The goal of this article is to explore current advancements in the field of arterial surgery and the biocompatibility concerns surrounding this area.

Content:

Biocompatibility is a mandatory requirement for biomaterials that are intended for clinical use. Biocompatibility is defined as the ability for a material to perform its intended function while eliciting no toxic or injurious effects on the biological system. Factors that can influence the biocompatibility of a material include: chemical, mechanical, and structural properties and their interaction with the biological environment.

Biomaterials need to meet the standards set by the International Standards Organization (ISO) for biocompatibility. Main considerations include; non toxic, nonthrombogenic, noncarcinogenic, nonantigenic and nonmutagenic.



The biological integration of devices for arterial use is modeled above at a tissue engineering level

The article describes “arterial equivalents” (AEs) — bioengineered vascular grafts designed to mimic human arteries structurally and functionally, rather than relying on synthetic tubes or non-arterial-derived grafts

The article reviews recent advances in how these engineered arteries are constructed, they consider materials and fabrication methods that are more compatible with living tissue than traditional synthetic grafts or rigid stents.

These can be used for further classification on the regulation and PDS revisions:

International standards for biocompatibility testing of biomaterials (4,5).

	Standards[a]	
Biological response	**ISO**	**ASTM**
Cytotoxicity	10993-5	F813-07; F895-84; F1027-06
Sensitization	10993-10	F720-81; F2147-01; F2148-07
Irritation	10993-10	F719-81; F749-98
Acute systemic toxicity	10993-11	F750-87
Subacute toxicity	10993-11	-
Genotoxicity	10993-3	E1262-88
Immunoresponsiveness	10993-20	F1906-98
Hemocompatibility	10993-4	F756-08
Chronic toxicity	10993-11	-
Carcinogenicity	10993-3	F1439-03
Degradation	10993-9; 10993-13	F1983-14
	10993-14; 10993-15	
Implantation	10993-6	F1408-97; F763-04; F1904-98 F981-04; F1983-99

Conclusions/action items: The scope of this article is beyond the application of our project but it was beneficial to see how artery and vein injuries are being treated beyond stent models. There is a lot of tissue engineering solutions in the works that can regenerate this tissue.

2025/10/17 - Classify Medical Devices

SOFIA DECICCO - Dec 10, 2025, 1:45 PM CST

Title: Codes and Standards for extraluminal arterial medical device

Date: 10/17/2025

Content by: Sofia DeCicco

Present: Sofia DeCicco

Goals: The goal of this entry is to document the device classification of an extraluminal stent

Citation: https://www.simplerqms.com/fda-medical-device-classification/

Content:

INTRAvascular stents (self-expanding or balloon-expandable) placed inside arteries or other vessels are classified as Class III medical devices by the FDA.

The FDA also issues guidance on non-clinical engineering assessments, material specifications (including for nitinol), surface finish, corrosion, nickel-ion release, mechanical performance, etc. for stents.

Our proposed device sits outside the artery (i.e. extraluminal), not inside the lumen, which changes some fundamental aspects that regulatory classification depends on. Because the device is outside the vessel, some risks typical of intravascular stents (e.g. intraluminal thrombosis, restenosis, in-stent restenosis, intimal hyperplasia, intravascular migration) might be reduced or changed in nature.

Conclusions/action items: Overall, the team our device sits between class III and class II classification. While intraluminal stents are class II medical devices, our stent will sit outside the artery and this reduces a lot of associated risks meaning it could be a class II device.

2025/09/17 - Device Operating Conditions

SOFIA DECICCO - Sep 18, 2025, 10:14 AM CDT

Title: Operating and In-vivo Device Conditions

Date: 09/17/2025

Content by: Sofia DeCicco

Present:

Goals: The goal of this entry is to research the operating conditions our device will be exposed to in the operating room and in the body. This will look at relative pressures, temperatures, and humidity exposures.

Content:

In vivo the device will be exposed and must maintain integrity at the following environmental conditions:

Human body temperature is within the range of 36.5-37.5 oC. Irreparable damage to organs can occur when body temperatures are outside of 32.2-41.1 oC [20].

Maximum arterial flow pressures can span from 80-120 mmHg for a healthy adult [7]:

Largest arterial pressures during systole is ~120 mmHg due to contraction of the heart that drives blood into arteries.

Largest arterial pressure during diastole is ~80 mmHg due to arterial recoil as the heart fills with blood.

Full humidity exposure since the device is continually exposed to blood and interstitial fluid. The device must therefore be resistant to corrosion.

Arterial diameters can vary with cardiac output such that any device must accommodate this fluctuation and not be too rigid.

During surgical handling in the operating room, the device may be subject to:

Sterilization through ethylene oxide which maintains atmospheric pressure of 101 kPa [21].

Operating room temperatures average 20 oC to 24 oC and relative humidity exposure of 40% to 60% [22].

Device must be easy to handle across all users wearing surgical gloves and removing device from sterile packaging.

Conclusions/action items:

The device must be designed to maintain its mechanical integrity and functionality under both in vivo and operating room conditions. This includes withstanding physiological temperatures (36.5–37.5 °C), arterial pressures up to ~120 mmHg, full humidity exposure from blood and interstitial fluid, and dimensional changes due to arterial compliance. In the surgical setting, the device must remain stable following sterilization, perform reliably under operating room temperature and humidity ranges, and be user-friendly for clinicians handling it in a sterile, gloved environment.

2025/09/16 - Sterilization Methods

SOFIA DECICCO - Sep 18, 2025, 10:15 AM CDT

Title: Ethylene Oxide Sterilization for Medical Devices

Date: 09/16/2025

Content by: Sofia DeCicco

Present:

Goals: The goal of this entry is to understand the process of ethylene oxide sterilization and how this impacts device sterility during shelf life. This will help us set conditions the device must be stored at and the expected shelf life.

Content:

The device will be free of any batteries, materials, or solutions that will have a set expiration date. Shelf life will therefore be determined by the sterility of the single-use device and package integrity.

About 50% of medical devices are sterilized with ethylene oxide due to its efficiency in sterilizing a variety of polymers, metals, or ceramics that are muti-layered or have difficult geometries [10]. This will be the main form of sterilization considered for the device's shelf life duration.

Sterility of medical devices exposed to ethylene oxide is at most 5 years [18]. This number is limited by packaging integrity, device material, handling and transportation, and environmental conditions. A minimum shelf life of 3 years will be achieved by considering the following:

Storing device in a cool and dry environment to prolong sterility. Condensation within packaging due to high humidity can impact sterility of the device.

Maximum relative humidity of 60% [19].

Temperatures range from 72 to 78 oC [19].

Positive air pressure relationship to adjacent areas [19].

Using a sealable and durable package to prevent tears that will eliminate sterile barriers.

Devices made from hard plastics and metals are less reactive to moisture and temperature maintaining sterility for longer periods of time. Use of softer more porous materials can reduce shelf life sterility.

Conclusions/action items:

Ethylene oxide sterilization provides an effective method to achieve sterility for complex medical devices, but the shelf life is ultimately limited by packaging integrity, material stability, and storage conditions. By using durable packaging, maintaining controlled temperature and humidity, and selecting materials with low reactivity to environmental factors, the device can reliably achieve a minimum shelf life of 3 years, with potential extension up to 5 years.

2025/10/11 - Mechanisms Behind Self-Expanding Stents

SOFIA DECICCO - Dec 10, 2025, 2:47 PM CST

Title: Mechanical Expansion of Nitinol Stents

Date: 11/10/2025

Content by: Sofia DeCicco

Present: N/A

Goals: the goal of this entry is to understand the expansion mechanisms of national at the artery level to contribute to any design specification in this area.

Citation: https://link.springer.com/article/10.1007/s00330-003-2022-5

Content:

Nitinol - shape memory and superelastic

Nitinol stents are typically manufactured to a diameter slightly larger than the target vessel size

- When constrained inside a delivery system (catheter, sheath), they remain compressed; upon release, they expand to their “memorized” larger shape, pressing outward against the vessel wall

Chronic outward force + radial resistive force: once deployed nitinol stents exert a low, chronic outward force that holds them to the artery wall

- they provide a significantly higher radial resistive force so they resist external compression or deformative forces helping keep the lumen open

large recoverable strains because of superelasticity

- Nitinol can undergo relatively large deformations while still returning to its original shape when load is removed
- the device can accommodate bending or twisting

Biocompatibility and corrosion resistance: despite high nickel content, properly processed Nitinol alloys show corrosion resistance and biocompatibility comparable to more conventional implant materials (like stainless steel)

For devices that undergo cyclic loads fatigue behavior is a major concern

- Nitinol’s non-linear, phase-transformation–based mechanics can lead to complex fatigue behavior that must be carefully characterized in design

Conclusions/action items: Overall, nitinol will have great mechanics for our application. Further investigation into geometry will be required by the team, but this article helped confirm the loader to concept feasibility.

2025/09/24 - Materials to Mimic Arteries

SOFIA DECICCO - Dec 10, 2025, 2:37 PM CST

Title: Material to Mimic Arterial Mechanical Composition

Date: 09/24/2025

Content by: Sofia DeCicco

Present: N/A

Goals: The goal of this entry is to explore potential material options that can be used to model and artery and our device on a bigger scale for final prototyping

Citation: https://www.sciencedirect.com/science/article/pii/S2590006421000144?utm

Content:

Arterial geometry heavily influences local mechanical loading: curvature and bends introduce bending stresses in addition to circumferential tension

Arteries exhibit directional dependence:

- Circumferential direction: highest stiffness, largest load-bearing capacity
- Axial direction: moderate stiffness; arteries maintain some pre-stretch even at rest
- Radial direction: very compliant; dominated by elastin and ground matrix

Material considerations:

Silicone Tubing

- Pros: stable, inexpensive, available in many diameters
- highly elastic, moderate nonlinear behavior.
- Limitation: not anisotropic, less stiff at high strain than collagen-dominated arterial walls

Latex Rubber

- Pros: strong strain-stiffening, good circumferential elasticity
- captures nonlinearity reasonably well
- Limitation: more isotropic and more compliant than real arteries, not accurate for multilayer behavior

Polyurethane (PU)

- Pros: can be cast with variable hardness, supports layered construction, has tunable elasticity
- closer to physiological stiffness
- Limitation: more complex to fabricate

3D-printed elastomers (TPU, flexible resin)

- Pros: customizable geometry; complex bends and branches modeled directly
- Limitation: mechanical behavior is less nonlinear

Conclusions/action items: There are a number of material considerations that can be used to model arteries but they all have associated limitations. It will be best for the team to use a material with easy access at the makerspace and practice on chicken arteries.

2025/09/28 - Nitinol Research

SOFIA DECICCO - Oct 17, 2025, 9:25 AM CDT

Title: Nitinol by Resonetics

Date: 09/28/2025

Content by: Sofia DeCicco

Present: N/A

Goals: The goal of this entry is to understand the manufacturing parameters of nitinol stents and book an appointment with an engineer at resonetics nitinol printing to see how they may be able to help the team print a stent.

Content:

The company resonetics are experts in nitinol processing and will be able to help us understand the processing impacts material properties.

Material has unique superelastic and shape-memory properties

Laser cutting: laser cutting the nitinol stent will help control for precise microscopic incisions and gas-assisted material removal

- Can achieve demanding geometrical features and tolerances
- Laser cutting specifications:
    - Feature sizes: 0.012mm - 10mm
    - Material thickness: 0.012mm - 0.5mm
    - Material diameter: 0.125mm - 10mm
    - Material length: 0.5mm - 3mm

Shape setting:

- Precise control of temperature and time is essential for shape setting nitinol
    - Material is heated to 500-550C to achieve and retain the pre-set shape

Electropolishing:

Electropolishing is an advanced electrochemical surface treatment that enhances the performance and reliability of nitinol components by removing a thin layer of material

- Improves finish, enhances corrosion resistance, enhances biocompatibility
- Electropolishing specifications:
    - Feature size: 0.012mm - 10mm
    - Wall thickness: 0.012mm - 0.1mm
    - Outside diameter: 0.0125mm - 10mm
    - Typical removal: 5-20% (5-10) microns depending on application and part size

Passivation: surface treatment that improves the corrosion resistance of metals via chemical treatment

- Thorough cleaning: removes unwanted surface materials
- Oxide layer formation: develops a stable and protective oxide layer (titanium dioxide) the enhances corrosion resistance and biocompatibility

Questions to ask during design consultation:

- What nitinol alloy/form do you recommend for an arterial stent (composition, Ni/Ti ratio, wire vs tube)?
- What are your minimum/typical diameters and wall thicknesses you can reliably start from for a 3 mm OD stent?
- For a 3.0 mm × 25.4 mm geometry, what are realistic tolerances for strut width, slot geometry, and overall length?

- Can you provide typical radial force, expansion profile, and elastic recoil data for stents you manufacture? Can you test to my design or to standard tests?
- Do you measure transformation temperatures (Af, Ms) on finished parts and after surface treatment? Can you control Af to a target range?
- Can you perform crimping/deployment testing with a delivery catheter or simulate radial compression?
- What are your minimum order quantities (prototype vs production) and expected lead times for: (a) prototype run (5–20 pieces), (b) pilot (100–500), (c) production (>1k)?
- How do you price: per-piece vs tooling/setup + per-piece? What are typical non-recurring engineering (NRE) costs for a new stent geometry?
- Can you provide a rough piece-cost estimate for 3 mm × 25.4 mm stents at different volumes and for prototype vs production? What drives cost most (material, yield, polishing)?
- Do you offer design iteration support and how do you handle changes (time/cost for rework)?

Work mostly with businesses very limited work with students

Laser printing from tubing

Introduction to nitinol paper on website - subtractive manufacturing removing material instead of adding it

Laser cutting, shape setting, electropolishing ID, OD, overall length

Help with development not design

Online store- nitionl tubing

Chamfer good resource to get sents

chamfr.com

resonetics.com

Conclusions/action items: The engineers at resonetics will not be able to help out team print our stent design since they primarily work with larger corporations that will serve the company long term. They did provide a few link to websites that cell extra nitinol stents. The team can look here and see if there are any similar in design and dimension that we could use for our purposes.

2025/11/17 - PTFE Loader Tubing

SOFIA DECICCO - Dec 10, 2025, 2:58 PM CST

Title: PTFE Material Properties

Date: 11/17/2025

Content by: Sofia DeCicco

Present: N/A

Goals: the goal of this entry is to document the material properties of PTFE tubing and understand if it will be a good fit for our project as a loader tube material

Citation: https://adtech.co.uk/about/news/ptfe-properties-benefits-uses

Content:

- High temperature tolerance/thermal stability: PTFE can operate continuously up to ~260 °C
- Its melting point is around ~327 °C (621 °F)
- Chemical inertness/chemical resistance: PTFE resists nearly all chemicals, solvents, acids, bases
- Very low coefficient of friction/non-stick surface!!
    - PTFE has one of the lowest friction coefficients among engineering plastics (dynamic coefficient around 0.05–0.10 depending on grade) and a highly non-stick surface
- Flexibility/elongation: PTFE can exhibit high elongation at break indicating ductility/flexibility
- Low water absorption/stability in moist environments
    - PTFE absorbs negligible water, resists swelling or degradation in wet or physiological environments
- Biocompatibility - PTFE is widely used in medical applications (e.g., liners, catheters, tubing) because it is inert and biologically stable
- Limitation: relatively low mechanical stiffness and strength, tendency for creep under sustained load, and difficulty in processing because it does not melt like conventional thermoplastics

Conclusions/action items: Given its chemical inertness, low friction, flexibility, biocompatibility, and resistance to moisture and corrosion, PTFE is a strong candidate for a loader or tubing material in our device.

2025/09/22 - Sock Clamp

SOFIA DECICCO - Sep 24, 2025, 10:19 PM CDT

Title: Sock Clamp Holder

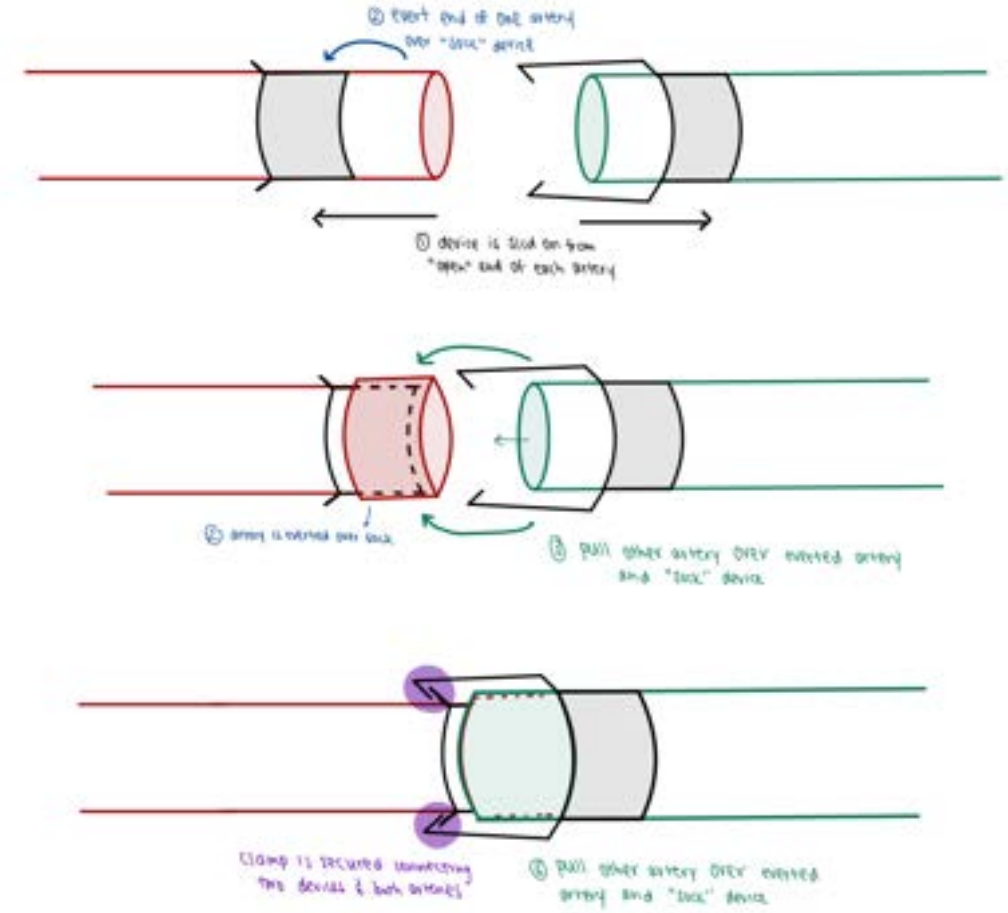
Date: 9/22/2025

Content by: Sofia DeCicco

Present: N/A

Goals: The goal of this entry is to document a potential design consideration and additional notes on client revisions.

Content:



This device involves two "sock" like mechanisms that will slide over the proximal/cut end of each artery. For reference the first device will slide on to the red artery and on this side only the artery will be everted back onto the device. The opposing green artery will then be pulled over the everted artery and device cuff. A supplemental cuff that will be attached to the green artery will be used to clamp on to the other device and secure contact. By everting one artery and pulling the other over, we are ensuring enough intima contact to promote healing of the artery.

client comments: the clients liked how this device provide sufficient intima contact and only involves inverting one artery. The clients think that is will be enough to only have one side of the device (attached to the red artery) and a suture can be made surrounding the whole to ensure its stability. The main note was that this design does not allow for a deformable/adjustable diameter. The device would ideally start at a smaller diameter to allow for easier eversion of the artery and reduce the bulk when pulling the opposing artery over. Once all parts are connected, the device would expand and allow for sufficient blood flow without the risk of clotting. These considerations will be added in future design ideas.

Conclusions/action items: The cuff-based design simplifies anastomosis by everting only one artery, ensuring strong intima contact and easier handling. Clients valued this simplicity and stability but emphasized the need for an expandable diameter to ease eversion, reduce bulk, and restore full flow. Future iterations will address these refinements.

2025/09/22- Expandable Stent

SOFIA DECICCO - Sep 25, 2025, 9:00 PM CDT

Title: Expandable Stent Arterial Coupler

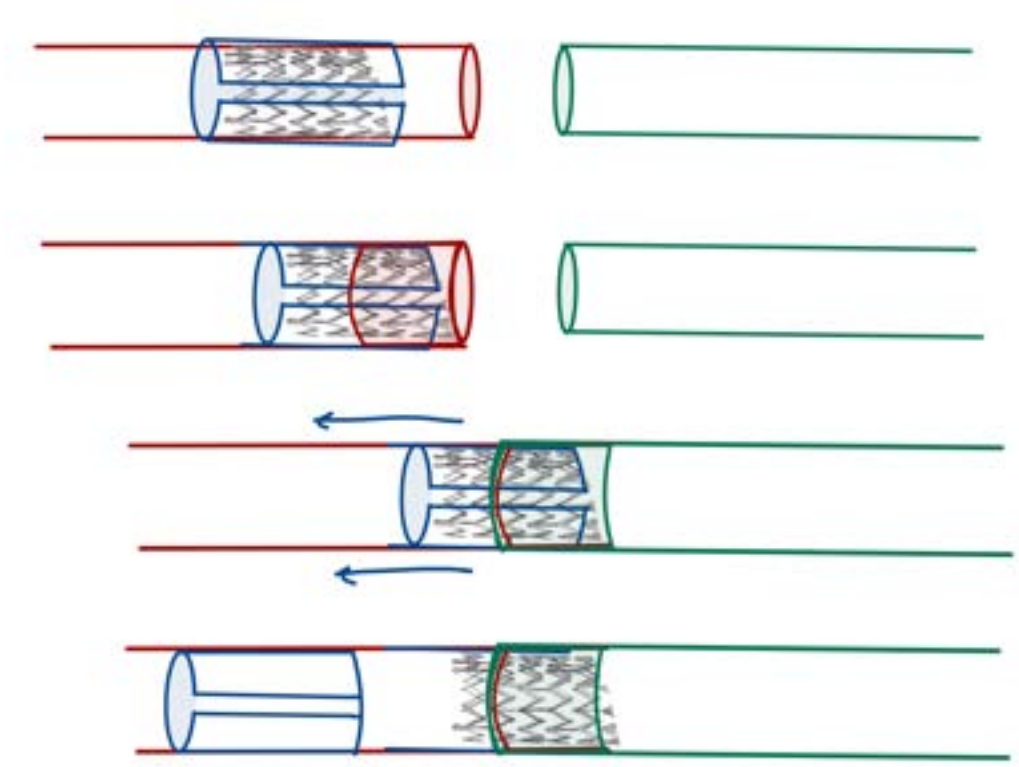
Date: 09/25/25

Content by: Sofia DeCicco

Present: N/A

Goals: The goal of this entry is to document a second iteration of the sock mechanism that is simplified and has an expandable diameter.

Content:



After receiving client feedback on the "sock clamp" design the client had a few notes to incorporate in a similar model. This incudes have a device that can be at a smaller diameter ~2mm during the actual anastomosis. This involves everting one artery end over the device and then stretching the opposing artery over the device. Once the two artery ends are secured over the device, the client would like the diameter of the device to expand to a larger diameter ~3mm that will allow for full flow through the artery to further reduce the risk of clotting.

This design involves a nitinol stent that will be inserted into a loading device that for now will restrict the inner lumen of the stent to be about 2 mm. The first artery, colored in red, will be everted over the stent and the restrictive tubing. The second artery, colored in green, will then be pulled over the device (still with the loading tube) and the everted artery. At this point, the tubing can be removed and the stent will expand in a controlled and slow manner has the tubing is pulled away. The slit in the elastic/deformable tubing will allow it to easily be removed from the artery.

Overall, this solution presents a great option that our clients were pleased about.

Conclusions/action items: Overall the client liked the intentions and mechanisms of this device. Future work will include extended research on the exact tubing material that will be biocompatible and easily removed from the artery.

2025/11/28 - Nitinol stent fabrication

SOFIA DECICCO - Dec 10, 2025, 3:06 PM CST

Title: Nitinol Stent Fabrication

Date: 11/28/2025

Content by: Sofia DeCicco

Present: N/A

Goals: the goal of this entry is to investigate methods of fabrication our own nitinol stent that will not require an expensive purchase but can still be used for some mechanical and feasibility testing

Content:

The attached PDF was used in the design selection and fabrication of a nitinol stent scaled up from our final design

Conclusions/action items: This stent can be used to better understand the heat treating requirements of nitinol and shape memory behaviors of nitinol wire

SOFIA DECICCO - Dec 10, 2025, 3:02 PM CST

Download

Patent_for_Nitinol_Stent_Design.pdf (1.98 MB)

2025/10/17 - Red Permit

SOFIA DECICCO - Oct 17, 2025, 1:44 PM CDT

Download

Red_Permit_.png (335 kB)

2025/10/17 - Green Permit

SOFIA DECICCO - Feb 12, 2024, 12:48 PM CST

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Green_Permit_.pdf (257 kB)

2025/10/17 - Biosaftey and OSHA training

SOFIA DECICCO - Feb 10, 2024, 4:15 PM CST

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BioSafety_and_OSHA.pdf (59.7 kB)

2025/10/17 - Research Animal Resources and Compliance (RARC)

SOFIA DECICCO - Oct 17, 2025, 1:38 PM CDT

Download

RARC_Training.png (252 kB)

2014/11/03 - Entry Guidelines

John Puccinelli - Sep 05, 2016, 1:18 PM CDT

Use this as a guide for every entry

- Every text entry of your notebook should have the **bold titles** below.
- Every page/entry should be **named starting with the date** of the entry's first creation/activity, subsequent material from future dates can be added later.

You can create a copy of the blank template by first opening the desired folder, clicking on "New", selecting "Copy Existing Page...", and then select "2014/11/03-Template")

Title: Descriptive title (i.e. Client Meeting)

Date: 9/5/2016

Content by: The one person who wrote the content

Present: Names of those present if more than just you (not necessary for individual work)

Goals: Establish clear goals for all text entries (meetings, individual work, etc.).

Content:

Contains clear and organized notes (also includes any references used)

Conclusions/action items:

Recap only the most significant findings and/or action items resulting from the entry.

2014/11/03 - Template

John Puccinelli - Nov 03, 2014, 3:20 PM CST

Title:

Date:

Content by:

Present:

Goals:

Content:

Conclusions/action items: